01/2011:40000

4. REAGENTS

Additional information for reagents that can only be fully identified by a trademark or whose availability is limited may be found in the KNOWLEDGE database on the EDQM website. This information is given only to make it easier to obtain such reagents and this does not suggest in any way that the mentioned suppliers are especially recommended or certified by the European Pharmacopoeia Commission or the Council of Europe. It is therefore acceptable to use reagents from another source provided that they comply with the standards of the Pharmacopoeia.

01/2011:40100

4.1. REAGENTS, STANDARD SOLUTIONS, BUFFER SOLUTIONS

Where the name of substance or a solution is followed by the letter R (the whole in italics), this indicates a reagent included in the following list. The specifications given for reagents do not necessarily guarantee their quality for use in medicines.

Within the description of each reagent there is a seven-figure reference code in italics (for example, *1002501*). This number, which will remain unchanged for a given reagent during subsequent revisions of the list, is used for identification purposes by the Secretariat, and users of the Pharmacopoeia may also find it useful, for example in the management of reagent stocks. The description may also include a CAS number (Chemical Abstract Service Registry Number) recognisable by its typical format, for example 9002-93-1.

Some of the reagents included in the list are toxic and are to be handled in conformity with good quality control laboratory practice.

Reagents in aqueous solution are prepared using *water R*. Where a reagent solution is described using an expression such as "hydrochloric acid (10 g/L HCl)", the solution is prepared by an appropriate dilution with *water R* of a more concentrated reagent solution specified in this chapter. Reagent solutions used in the limit tests for barium, calcium and sulfates are prepared using *distilled water R*. Where the name of the solvent is not stated, an aqueous solution is intended.

The reagents and reagent solutions are to be stored in well-closed containers. The labelling should comply with the relevant national legislation and international agreements.

01/2011:40101

4.1.1. REAGENTS

Acacia. *1000100.*

See *Acacia (0307)*.

Acacia solution. *1000101.*

Dissolve 100 g of *acacia R* in 1000 mL of *water R*. Stir with a mechanical stirrer for 2 h. Centrifuge at about 2000 *g* for 30 min to obtain a clear solution.

Storage: in polyethylene containers of about 250 mL capacity at a temperature of 0 °C to – 20 °C.

Acebutolol hydrochloride. *1148900.* [34381-68-5].

See *Acebutolol hydrochloride (0871)*.

Acetal. $C_6H_{14}O_2$. (M_r 118.2). *1112300.* [105-57-7]. Acetaldehyde diethyl acetal. 1,1-Diethoxyethane.

Clear, colourless, volatile liquid, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: about 0.824.

n_D^{20}: about 1.382.

bp: about 103 °C.

Acetaldehyde. C_2H_4O. (M_r 44.1). *1000200.* [75-07-0]. Ethanal.

Clear, colourless flammable liquid, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: about 0.788.

n_D^{20}: about 1.332.

bp: about 21 °C.

Acetaldehyde ammonia trimer trihydrate. $C_6H_{15}N_3{,}3H_2O$. (M_r 183.3). *1133500.* [58052-80-5]. 2,4,6-Trimethylhexahydro-1, 3,5-triazine trihydrate.

mp: 95 °C to 97 °C.

Acetic acid, anhydrous. $C_2H_4O_2$. (M_r 60.1). *1000300.* [64-19-7].

Content: minimum 99.6 per cent *m/m* of $C_2H_4O_2$.

Colourless liquid or white or almost white, shining, fern-like crystals, miscible with or very soluble in water, in ethanol (96 per cent), in glycerol (85 per cent), and in most fatty and essential oils.

d_{20}^{20}: 1.052 to 1.053.

bp: 117 °C to 119 °C.

A 100 g/L solution is strongly acid (*2.2.4*).

A 5 g/L solution neutralised with *dilute ammonia R2* gives reaction (b) of acetates (*2.3.1*).

Freezing point (*2.2.18*): minimum 15.8 °C.

Water (*2.5.12*): maximum 0.4 per cent. If the water content is more than 0.4 per cent it may be adjusted by adding the calculated amount of *acetic anhydride R*.

Storage: protected from light.

Acetic acid, glacial. $C_2H_4O_2$. (M_r 60.1). *1000400.* [64-19-7].

See *Acetic acid, glacial (0590)*.

Acetic acid. *1000401.*

Content: 290 g/L to 310 g/L of $C_2H_4O_2$ (M_r 60.1).

Dilute 30 g of *glacial acetic acid R* to 100 mL with *water R*.

Acetic acid, dilute. *1000402.*

Content: 115 g/L to 125 g/L of $C_2H_4O_2$ (M_r 60.1).

Dilute 12 g of *glacial acetic acid R* to 100 mL with *water R*.

Acetic anhydride. $C_4H_6O_3$. (M_r 102.1). *1000500.* [108-24-7].

Content: minimum 97.0 per cent *m/m* of $C_4H_6O_3$.

Clear, colourless liquid.

bp: 136 °C to 142 °C.

Assay. Dissolve 2.00 g in 50.0 mL of *1 M sodium hydroxide* in a ground-glass-stoppered flask and boil under a reflux condenser for 1 h. Titrate with *1 M hydrochloric acid*, using 0.5 mL of *phenolphthalein solution R* as indicator. Calculate the number of millilitres of *1 M sodium hydroxide* required for 1 g (n_1). Dissolve 2.00 g in 20 mL of *cyclohexane R* in a ground-glass-stoppered flask, cool in ice and add a cold mixture of 10 mL of *aniline R* and 20 mL of *cyclohexane R*. Boil the mixture under a reflux condenser for 1 h, add 50.0 mL of *1 M sodium hydroxide* and shake vigorously. Titrate with *1 M hydrochloric acid*, using 0.5 mL of *phenolphthalein solution R* as indicator. Calculate the number of millilitres of *1 M sodium hydroxide* required for 1 g (n_2). Calculate the percentage of $C_4H_6O_3$ from the following expression:

$$10.2\,(n_1 - n_2)$$

Acetic anhydride solution R1. *1000501.*

Dissolve 25.0 mL of *acetic anhydride R* in *anhydrous pyridine R* and dilute to 100.0 mL with the same solvent.

Storage: protected from light and air.

Acetic anhydride - sulfuric acid solution. *1000502.*

Carefully mix 5 mL of *acetic anhydride R* with 5 mL of *sulfuric acid R*. Add dropwise and with cooling to 50 mL of *anhydrous ethanol R*.

Prepare immediately before use.

Acetone. *1000600.* [67-64-1].

See *Acetone (0872)*.

Acetonitrile. C_2H_3N. (M_r 41.05). *1000700.* [75-05-8]. Methyl cyanide. Ethanenitrile.

Clear, colourless liquid, miscible with water, with acetone and with methanol.

d_{20}^{20}: about 0.78.

n_D^{20}: about 1.344.

A 100 g/L solution is neutral to litmus paper.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 80 °C and 82 °C.

Acetonitrile used in spectrophotometry complies with the following additional test.

Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 98 per cent from 255 nm to 420 nm.

Acetonitrile for chromatography. *1000701.*

See *Acetonitrile R*.

Acetonitrile used in chromatography complies with the following additional tests.

Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 98 per cent from 240 nm.

Minimum purity (*2.2.28*): 99.8 per cent.

Acetonitrile R1. *1000702.*

Complies with the requirements prescribed for *acetonitrile R* and with the following additional requirements.

Content: minimum 99.9 per cent.

Absorbance (*2.2.25*): maximum 0.10, determined at 200 nm using *water R* as the compensation liquid.

Acetoxyvalerenic acid. $C_{17}H_{24}O_4$. (M_r 292.4). *1165800.* [81397-67-3]. (2*E*)-3-[(1*RS*,4*S*,7*R*,7a*R*)-1-(Acetyloxy)-3,7-dimethyl-2,4,5,6,7,7a-hexahydro-1*H*-inden-4-yl]-2-methylprop-2-enoic acid.

Colourless or pale yellow viscous oil.

Absorbance (*2.2.25*). A solution in *methanol R* shows an absorption maximum at about 216 nm.

Acetylacetamide. $C_4H_7NO_2$. (M_r 101.1). *1102600.* [5977-14-0]. 3-Oxobutanamide.

mp: 53 °C to 56 °C.

Acetylacetone. $C_5H_8O_2$. (M_r 100.1). *1000900.* [123-54-6]. 2,4-Pentanedione.

Colourless or slightly yellow, easily flammable liquid, freely soluble in water, miscible with acetone, with ethanol (96 per cent) and with glacial acetic acid.

n_D^{20}: 1.452 to 1.453.

bp: 138 °C to 140 °C.

Acetylacetone reagent R1. *1000901.*

To 100 mL of *ammonium acetate solution R* add 0.2 mL of *acetylacetone R*.

***N*-Acetyl-ε-caprolactam.** $C_8H_{13}NO_2$. (M_r 155.2). *1102700.* [1888-91-1]. *N*-Acetylhexane-6-lactam.

Colourless liquid, miscible with anhydrous ethanol.

d_{20}^{20}: about 1.100.

n_D^{20}: about 1.489.

bp: about 135 °C.

Acetyl chloride. C_2H_3ClO. (M_r 78.5). *1000800.* [75-36-5].

Clear, colourless liquid, flammable, decomposes in contact with water and with ethanol (96 per cent), miscible with ethylene chloride.

d_{20}^{20}: about 1.10.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 49 °C and 53 °C.

Acetylcholine chloride. $C_7H_{16}ClNO_2$. (M_r 181.7). *1001000.* [60-31-1].

Crystalline powder, very soluble in cold water and in ethanol (96 per cent). It decomposes in hot water and in alkalis.

Storage: at −20 °C.

Acetyleugenol. $C_{12}H_{14}O_3$. (M_r 206.2). *1100700.* [93-28-7]. 2-Methoxy-4-(2-propenyl)phenylacetate.

Yellow coloured, oily liquid, practically insoluble in water, freely soluble in ethanol (96 per cent).

n_D^{20}: about 1.521.

bp: 281 °C to 282 °C.

Acetyleugenol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Clove oil (1091)*.

Test solution. The substance to be examined.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

***N*-Acetylglucosamine.** $C_8H_{15}NO_6$. (M_r 221.2). *1133600.* [7512-17-6]. 2-(Acetylamino)-2-deoxy-D-glucopyranose.

mp: about 202 °C.

Acetyl-11-keto-β-boswellic acid. $C_{32}H_{48}O_5$. (M_r 512.7). *1167700.* [67416-61-9]. 3α-(Acetyloxy)-11-oxours-12-en-24-oic acid. (4β)-3α-(Acetyloxy)-11-oxours-12-en-23-oic acid.

White or almost white powder, insoluble in water, soluble in acetone, in anhydrous ethanol and in methanol.

mp: 271 °C to 274 °C.

Acetyl-11-keto-β-boswellic acid used in liquid chromatography complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph on *Indian frankincense (2310)*.

Content: minimum 90 per cent, calculated by the normalisation procedure.

***N*-Acetylneuraminic acid.** $C_{11}H_{19}NO_9$. (M_r 309.3). *1001100.* [131-48-6]. *O*-Sialic acid.

White or almost white acicular crystals, soluble in water and in methanol, slightly soluble in anhydrous ethanol, practically insoluble in acetone.

$[\alpha]_D^{20}$: about −36, determined on a 10 g/L solution.

mp: about 186 °C, with decomposition.

***N*-Acetyltryptophan.** $C_{13}H_{14}N_2O_3$. (M_r 246.3). *1102800.* [1218-34-4]. 2-Acetylamino-3-(indol-3-yl)propanoic acid.

White or almost white powder or colourless crystals, slightly soluble in water. It dissolves in dilute solutions of alkali hydroxides.

mp: about 205 °C.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Tryptophan (1272)*.

Test solution. Dissolve 10.0 mg in a mixture of 10 volumes of *acetonitrile R* and 90 volumes of *water R* and dilute to 100.0 mL with the same mixture of solvents.

Content: minimum 99.0 per cent, calculated by the normalisation procedure.

Acetyltyrosine ethyl ester. $C_{13}H_{17}NO_4,H_2O$. (M_r 269.3). *1001200.* [36546-50-6]. *N*-Acetyl-L-tyrosine ethyl ester monohydrate. Ethyl (*S*)-2-acetamido-3-(4-hydroxyphenyl)propionate monohydrate.

White or almost white, crystalline powder suitable for the assay of chymotrypsin.

$[\alpha]_D^{20}$: + 21 to + 25, determined on a 10 g/L solution in *ethanol (96 per cent) R*.

$A_{1\,cm}^{1\%}$: 60 to 68, determined at 278 nm in *ethanol (96 per cent) R*.

Acetyltyrosine ethyl ester, 0.2 M. *1001201.*

Dissolve 0.54 g of *acetyltyrosine ethyl ester R* in *ethanol (96 per cent) R* and dilute to 10.0 mL with the same solvent.

Acid blue 83. $C_{45}H_{44}N_3NaO_7S_2$. (M_r 826). *1012200.* [6104-59-2].

Colour Index No. 42660.
Brilliant blue R. Coomassie brilliant blue R 250.

Brown powder insoluble in cold water, slightly soluble in boiling water and in anhydrous ethanol, soluble in sulfuric acid, glacial acetic acid and in dilute solutions of alkali hydroxides.

Acid blue 90. $C_{47}H_{48}N_3NaO_7S_2$. (M_r 854). *1001300.* [6104-58-1].

Colour Index No. 42655.
Sodium [4-[[4-[(4-ethoxyphenyl)amino]phenyl][[4-(ethyl)(3-sulfonatobenzyl)amino]phenyl]methylene]cyclo-hexa-2,5-dien-1-ylidene](ethyl)-(3-sulfonatobenzyl)ammonium.

A dark brown powder, with a violet sheen and some particles having a metallic lustre, soluble in water and in anhydrous ethanol.

$A_{1\,cm}^{1\%}$: greater than 500, determined at 577 nm in a 0.01 g/L solution in buffer solution pH 7.0 and calculated with reference to the dried substance.

Loss on drying (*2.2.32*): maximum 5.0 per cent, determined on 0.500 g by drying in an oven at 105 °C.

Acid blue 92. $C_{26}H_{16}N_3Na_3O_{10}S_3$. ($M_r$ 696). *1001400.* [3861-73-2].

Colour Index No. 13390.
Coomassie blue. Anazolene sodium. Trisodium 8-hydroxy-4′-(phenylamino)azonaphthalene-3,5′,6-trisulfonate.

Dark blue crystals, soluble in water, in acetone and in ethylene glycol monoethylether, slightly soluble in ethanol (96 per cent).

Acid blue 92 solution. *1001401.*

Dissolve 0.5 g of *acid blue 92 R* in a mixture of 10 mL of *glacial acetic acid R*, 45 mL of *ethanol (96 per cent) R* and 45 mL of *water R*.

Acid blue 93. $C_{37}H_{27}N_3Na_2O_9S_3$. ($M_r$ 800). *1134200.* [28983-56-4].

Colour Index No. 42780.
Methyl blue. Poirrier blue.

Mixture of triphenylrosaniline di- and trisulfonate and of triphenylpararosaniline.

Dark blue powder.

Colour change: pH 9.4 to pH 14.0.

Acid blue 93 solution. *1134201.*

Dissolve 0.2 g of *acid blue 93 R* in *water R* and dilute to 100 mL with the same solvent.

Acrylamide. C_3H_5NO. (M_r 71.1). *1001500.* [79-06-1].
Propenamide.

Colourless or white flakes or a white or almost white, crystalline powder, very soluble in water and in methanol, freely soluble in anhydrous ethanol.

mp: about 84 °C.

30 per cent acrylamide/bisacrylamide (29:1) solution. *1001501.*

Prepare a solution containing 290 g of *acrylamide R* and 10 g of *methylenebisacrylamide R* per litre of *water R*. Filter.

30 per cent acrylamide/bisacrylamide (36.5:1) solution. *1001502.*

Prepare a solution containing 292 g of *acrylamide R* and 8 g of *methylenebisacrylamide R* per litre of *water R*. Filter.

Acrylic acid. $C_3H_4O_2$. (M_r 72.1). *1133700.* [79-10-7].
Prop-2-enoic acid. Vinylformic acid.

Content: minimum 99 per cent.

It is stabilised with 0.02 per cent of hydroquinone monomethyl ether.

Corrosive liquid, miscible with water and ethanol (96 per cent). It polymerises readily in the presence of oxygen.

d_{20}^{20}: about 1.05.

n_D^{20}: about 1.421.

bp: about 141 °C.

mp: 12 °C to 15 °C.

Acteoside. $C_{29}H_{36}O_{15}$. (M_r 624.6). *1145100.* [61276-17-3]. 2-(3,4-Dihydroxyphenyl)ethyl 3-*O*-(6-deoxy-α-L-mannopyranosyl)-4-*O*-[(2*E*)-3-(3,4-dihydroxyphenyl)prop-2-enoyl]-β-D-glucopyranoside.

Light yellowish powder, freely soluble in water and in methanol.

mp: about 140 °C, with decomposition.

Adenine. *1172800.* [73-24-5].

See *Adenine (0800)*.

Adenosine. $C_{10}H_{13}N_5O_4$. (M_r 267.2). *1001600.* [58-61-7].
6-Amino-9-β-D-ribofuranosyl-9*H*-purine.

White or almost white, crystalline powder, slightly soluble in water, practically insoluble in acetone and in ethanol (96 per cent). It dissolves in dilute solutions of acids.

mp: about 234 °C.

Adipic acid. $C_6H_{10}O_4$. (M_r 146.1). *1095600.* [124-04-9].

Prisms, freely soluble in methanol, soluble in acetone, practically insoluble in light petroleum.

mp: about 152 °C.

Adrenaline. $C_9H_{13}NO_3$. (M_r 183.2). *1155000.* [51-43-4].
(1*R*)-1-(3,4-Dihydroxyphenyl)-2-(methylamino)ethanol. 4-[(1*R*)-1-hydroxy-2-(methylamino)ethyl]benzene-1,2-diol.

White or almost white powder, gradually becoming brown on exposure to light and air, very slightly soluble in water and in ethanol (96 per cent), insoluble in acetone. It dissolves in dilute solutions of mineral acids and alkali hydroxides.

mp: about 215 °C.

Adrenalone hydrochloride. $C_9H_{12}ClNO_3$. (M_r 217.7). *1155100.* [62-13-5]. 1-(3,4-Dihydroxyphenyl)-2-(methylamino)ethanone hydrochloride. 3′,4′-Dihydroxy-2-(methylamino)acetophenone hydrochloride.

Pale yellow crystals, freely soluble in water, soluble in ethanol (96 per cent).

mp: about 244 °C.

Aescin. *1001700.* [6805-41-0].

A mixture of related saponins obtained from the seeds of *Aesculus hippocastanum* L.

Fine, almost white or slightly reddish or yellowish, amorphous powder.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Senega root (0202)*: apply 20 µL of the solution; after spraying with *anisaldehyde solution R* and heating, the chromatogram shows a principal band with an R_F of about 0.4.

Aflatoxin B_1. $C_{17}H_{12}O_6$. (M_r 312.3). *1166000.* [1162-65-8].
(6a*R*,9a*S*)-4-Methoxy-2,3,6a,9a-tetrahydrocyclopenta[*c*]furo[3′,2′:4,5]furo[2,3-*h*][1]benzopyran-1,11-dione.

White or faint yellow crystals.

Agarose/cross-linked polyacrylamide. *1002200.*

Agarose trapped within a cross-linked polyacrylamide network; it is used for the separation of globular proteins with relative molecular masses of 2×10^4 to 35×10^4.

Agarose-DEAE for ion-exchange chromatography. *1002100.* [57407-08-6].

Cross-linked agarose substituted with diethylaminoethyl groups, presented as beads.

Agarose for chromatography. *1001800.* [9012-36-6].

Swollen beads 60-140 µm in diameter presented as a 4 per cent suspension in *water R*.

Used in size-exclusion chromatography for the separation of proteins with relative molecular masses of 6×10^4 to 20×10^6 and of polysaccharides with relative molecular masses of 3×10^3 to 5×10^6.

Agarose for chromatography, cross-linked. *1001900.* [61970-08-9].

Prepared from agarose by reaction with 2,3-dibromopropanol in strongly alkaline conditions.

It occurs as swollen beads 60-140 µm in diameter and is presented as a 4 per cent suspension in *water R*.

Used in size-exclusion chromatography for the separation of proteins with relative molecular masses of 6×10^4 to 20×10^6 and of polysaccharides with relative molecular masses of 3×10^3 to 5×10^6.

Agarose for chromatography, cross-linked R1. *1001901.* [65099-79-8].

Prepared for agarose by reaction with 2,3-dibromopropanol in strongly alkaline conditions.

It occurs as swollen beads 60-140 µm in diameter and is presented as a 4 per cent suspension in *water R*.

Used in size-exclusion chromatography for the separation of proteins with relative molecular masses of 7×10^4 to 40×10^6 and of polysaccharides with relative molecular masses of 1×10^5 to 2×10^7.

Agarose for electrophoresis. *1002000.* [9012-36-6].

A neutral, linear polysaccharide, the main component of which is derived from agar.

White or almost white powder, practically insoluble in cold water, very slightly soluble in hot water.

Agnuside. $C_{22}H_{26}O_{11}$. (M_r 466.4). *1162000.* [11027-63-7]. (1*RS*,4a*SR*,5*RS*,7a*RS*)-5-Hydroxy-7-[[(4-hydroxybenzoyl)oxy]methyl]-1,4a,5,7a-tetrahydrocyclopenta[*c*]pyran-1-yl β-D-glucopyranoside.

White or almost white crystals.

Alanine. *1102900.* [56-41-7].

See *Alanine (0752)*.

β-Alanine. *1004500.* [107-95-9].

See *3-aminopropionic acid R*.

Albumin, bovine. *1002300.* [9048-46-8].

Bovine serum albumin containing about 96 per cent of protein.

White to light-yellowish-brown powder.

Water (*2.5.12*): maximum 3.0 per cent, determined on 0.800 g.

Bovine albumin used in the assay of tetracosactide should be pyrogen-free, free from proteolytic activity, when examined by a suitable means, for example using chromogenic substrate, and free from corticosteroid activity determined by measurement of fluorescence as prescribed in the biological assay of Tetracosactide (0644).

Albumin, human. *1133800.*

Human serum albumin containing not less than 96 per cent of albumin.

Albumin solution, human. *1002400.* [9048-46-8].

See *Human albumin solution (0255)*.

Albumin solution, human R1. *1002401.*

Dilute *human albumin solution R* with a 9 g/L solution of *sodium chloride R* to a concentration of 1 g/L of protein. Adjust the pH to 3.5-4.5 with *glacial acetic acid R*.

Alcohol. *1002500.* [64-17-5].

See *Ethanol (96 per cent) R*.

Alcohol (*x* per cent *V/V*). *1002502.*

See *Ethanol (x per cent V/V) R*.

Alcohol, aldehyde-free. *1002501.*

Mix 1200 mL of *ethanol (96 per cent) R* with 5 mL of a 400 g/L solution of *silver nitrate R* and 10 mL of a cooled 500 g/L solution of *potassium hydroxide R*. Shake, allow to stand for a few days and filter. Distil the filtrate immediately before use.

Aldehyde dehydrogenase. *1103000.*

Enzyme obtained from baker's yeast which oxidises acetaldehyde to acetic acid in the presence of nicotinamide-adenine dinucleotide, potassium salts and thiols, at pH 8.0.

Aldehyde dehydrogenase solution. *1103001.*

Dissolve in *water R* a quantity of *aldehyde dehydrogenase R*, equivalent to 70 units and dilute to 10 mL with the same solvent. This solution is stable for 8 h at 4 °C.

Aldrin. $C_{12}H_8Cl_6$. (M_r 364.9). *1123100.* [309-00-2].

bp: about 145 °C.

mp: about 104 °C.

A suitable certified reference solution (10 ng/µL in cyclohexane) may be used.

Aleuritic acid. $C_{16}H_{32}O_5$. (M_r 304.4). *1095700.* [533-87-9]. (9*RS*,10*SR*)-9,10,16-Trihydroxyhexadecanoic acid.

White or almost white powder, greasy to the touch, soluble in methanol.

mp: about 101 °C.

Alizarin S. $C_{14}H_7NaO_7S,H_2O$. (M_r 360.3). *1002600.* [130-22-3].

Schultz No. 1145.

Colour Index No. 58005.

Sodium 1,2-dihydroxyanthraquinone-3-sulfonate monohydrate.

Sodium 3,4-dihydroxy-9,10-dioxo-9,10-dihydroanthracene-2-sulfonate monohydrate.

Orange-yellow powder, freely soluble in water and in ethanol (96 per cent).

Alizarin S solution. *1002601.*

A 1 g/L solution.

Test for sensitivity. If alizarin S solution is used for the standardisation of *0.05 M barium perchlorate*, it shows a colour change from yellow to orange-red when it is tested according to the standardisation of *0.05 M barium perchlorate* (*4.2.2*).

Colour change: pH 3.7 (yellow) to pH 5.2 (violet).

Aluminium. Al. (A_r 26.98). *1118200.* [7429-90-5].

White or almost white, malleable, flexible, bluish metal, available as bars, sheets, powder, strips or wire. In moist air an oxide film forms which protects the metal from corrosion.

Analytical grade.

Aluminium chloride. $AlCl_3,6H_2O$. (M_r 241.4). *1002700.* [7784-13-6]. Aluminium chloride hexahydrate.

Content: minimum 98.0 per cent of $AlCl_3,6H_2O$.

White or slightly yellowish, crystalline powder, hygroscopic, freely soluble in water and in ethanol (96 per cent).

Storage: in an airtight container.

Aluminium chloride reagent. *1002702.*

Dissolve 2.0 g of *aluminium chloride R* in 100 mL of a 5 per cent *V/V* solution of *glacial acetic acid R* in *methanol R*.

Aluminium chloride solution. *1002701.*

Dissolve 65.0 g of *aluminium chloride R* in *water R* and dilute to 100 mL with the same solvent. Add 0.5 g of *activated charcoal R*, stir for 10 min, filter and add to the filtrate, with continuous stirring, sufficient of a 10 g/L solution of *sodium hydroxide R* (about 60 mL) to adjust the pH to about 1.5.

Aluminium nitrate. $Al(NO_3)_3,9H_2O$. (M_r 375.1). *1002800.* [7784-27-2]. Aluminium nitrate nonahydrate.

Crystals, deliquescent, very soluble in water and ethanol (96 per cent), very slightly soluble in acetone.

Storage: in an airtight container.

Aluminium oxide, anhydrous. *1002900.* [1344-28-1].

Aluminium oxide, consisting of γ-Al_2O_3, dehydrated and activated by heat treatment.

Particle size: 75 µm to 150 µm.

Aluminium oxide, basic. *1118300.*

A basic grade of *anhydrous aluminium oxide R* suitable for column chromatography.

pH (*2.2.3*). Shake 1 g with 10 mL of *carbon dioxide-free water R* for 5 min. The pH of the suspension is 9 to 10.

Aluminium oxide, neutral. *1118400.*

See *Aluminium oxide, hydrated (0311)*.

Aluminium potassium sulfate. *1003000.* [7784-24-9].

See *Alum (0006)*.

Americium-243 spiking solution. *1167500.*

Contains 50 Bq/L ^{243}Pu and a 134 g/L solution of *lanthanum chloride heptahydrate R* in a 103 g/L solution of *hydrochloric acid R*.

Amido black 10B. $C_{22}H_{14}N_6Na_2O_9S_2$. ($M_r$ 617). *1003100.* [1064-48-8].

Schultz No. 299.

Colour Index No. 20470.

Disodium 5-amino-4-hydroxy-6-[(4-nitrophenyl)azo]-3-(phenylazo)naphthalene-2,7-disulfonate.

Dark-brown to black powder, sparingly soluble in water, soluble in ethanol (96 per cent).

Amido black 10B solution. *1003101.*

A 5 g/L solution of *amido black 10B R* in a mixture of 10 volumes of *acetic acid R* and 90 volumes of *methanol R*.

Aminoazobenzene. $C_{12}H_{11}N_3$. (M_r 197.2). *1003200.* [60-09-3].

Colour Index No. 11000.

4-(Phenylazo)aniline.

Brownish-yellow needles with a bluish tinge, slightly soluble in water, freely soluble in ethanol (96 per cent).

mp: about 128 °C.

2-Aminobenzoic acid. $C_7H_7NO_2$. (M_r 137.1). *1003400.* [118-92-3]. Anthranilic acid.

A white or pale-yellow, crystalline powder, sparingly soluble in cold water, freely soluble in hot water, in ethanol (96 per cent) and in glycerol. Solutions in ethanol (96 per cent) or in ether and, particularly, in glycerol show a violet fluorescence.

mp: about 145 °C.

3-Aminobenzoic acid. $C_7H_7NO_2$. (M_r 137.1). *1147400.* [99-05-8].

White or almost white crystals. An aqueous solution turns brown on standing in air.

mp: about 174 °C.

Storage: in an airtight container, protected from light.

4-Aminobenzoic acid. $C_7H_7NO_2$. (M_r 137.1). *1003300.* [150-13-0].

White or almost white, crystalline powder, slightly soluble in water, freely soluble in ethanol (96 per cent), practically insoluble in light petroleum.

mp: about 187 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Procaine hydrochloride (0050)*; the chromatogram shows only one principal spot.

Storage: protected from light.

4-Aminobenzoic acid solution. *1003301.*

Dissolve 1 g of *4-aminobenzoic acid R* in a mixture of 18 mL of *anhydrous acetic acid R*, 20 mL of *water R* and 1 mL of *phosphoric acid R*. Immediately before use, mix 2 volumes of the solution with 3 volumes of *acetone R*.

***N*-(4-Aminobenzoyl)-L-glutamic acid.** $C_{12}H_{14}N_2O_5$. (M_r 266.3). *1141700.* [4271-30-1]. ABGA. (2*S*)-2-[(4-Aminobenzoyl)amino]pentanedioic acid.

White or almost white, crystalline powder.

mp: about 175 °C, with decomposition.

4-Aminobutanoic acid. $C_4H_9NO_2$. (M_r 103.1). *1123200.* [56-12-2]. γ-Aminobutyric acid. GABA.

Leaflets from methanol and ether, needles from water and ethanol (96 per cent). Freely soluble in water, practically insoluble or slightly soluble in other solvents.

mp: about 202 °C (decreases on rapid heating).

Aminobutanol. $C_4H_{11}NO$. (M_r 89.1). *1003500.* [5856-63-3]. 2-Aminobutanol.

Oily liquid, miscible with water, soluble in ethanol (96 per cent).

d_{20}^{20}: about 0.94.

n_D^{20}: about 1.453.

bp: about 180 °C.

Aminochlorobenzophenone. $C_{13}H_{10}ClNO$. (M_r 231.7). *1003600.* [719-59-5]. 2-Amino-5-chlorobenzophenone.

Yellow, crystalline powder, practically insoluble in water, freely soluble in acetone, soluble in ethanol (96 per cent).

mp: about 97 °C.

Content: minimum 95.0 per cent.

Storage: protected from light.

4-Aminofolic acid. $C_{19}H_{20}N_8O_5$. (M_r 440.4). *1163700.* [54-62-6]. (2*S*)-2-[[4-[[(2,4-Diaminopteridin-6-yl)methyl]amino]benzoyl]amino]pentanedioic acid. *N*-[4-[[(2,4-Diaminopteridin-6-yl)methyl]amino]benzoyl]-L-glutamic acid. Aminopterine.

Yellowish powder.

mp: about 230 °C.

6-Aminohexanoic acid. $C_6H_{13}NO_2$. (M_r 131.2). *1103100.* [60-32-2].

Colourless crystals, freely soluble in water, sparingly soluble in methanol, practically insoluble in anhydrous ethanol.

mp: about 205 °C.

Aminohippuric acid. $C_9H_{10}N_2O_3$. (M_r 194.2). *1003700.* [61-78-9]. (4-Aminobenzamido)acetic acid.

White or almost white powder, sparingly soluble in water, soluble in ethanol (96 per cent).

mp: about 200 °C.

Aminohippuric acid reagent. *1003701.*

Dissolve 3 g of *phthalic acid R* and 0.3 g of *aminohippuric acid R* in *ethanol (96 per cent) R* and dilute to 100 mL with the same solvent.

Aminohydroxynaphthalenesulfonic acid. $C_{10}H_9NO_4S$. (M_r 239.3). *1112400.* [116-63-2]. 4-Amino-3-hydroxynaphthalene-1-sulfonic acid.

White or grey needles, turning pink on exposure to light, especially when moist, practically insoluble in water and in ethanol (96 per cent), soluble in solutions of alkali hydroxides and in hot solutions of sodium metabisulfite.

Storage: protected from light.

Aminohydroxynaphthalenesulfonic acid solution. *1112401.*

Mix 5.0 g of *anhydrous sodium sulfite R* with 94.3 g of *sodium hydrogensulfite R* and 0.7 g of *aminohydroxynaphthalenesulfonic acid R*. Dissolve 1.5 g of the mixture in *water R* and dilute to 10.0 mL with the same solvent. Prepare the solution daily.

***cis*-Aminoindanol.** $C_9H_{11}NO$. (M_r 149.2). *1168300.* [126456-43-7]. (1*S*,2*R*)-1-Amino-2,3-dihydro-1*H*-inden-2-ol. (−)-*cis*-1-Aminoindan-2-ol.

Content: minimum 98.0 per cent (sum of enantiomers, determined by gas chromatography).

$[\alpha]_D^{20}$: −69 to −59, determined on a 2 g/L solution in *chloroform R*.

mp: 118 °C to 122 °C.

Aminomethylalizarindiacetic acid. $C_{19}H_{15}NO_8,2H_2O$. (M_r 421.4). *1003900.* [3952-78-1]. 2,2′-[(3,4-dihydroxy-anthraquinon-3-yl)methylenenitrilo]diacetic acid dihydrate. Alizarin complexone dihydrate.

Fine, pale brownish-yellow or orange-brown powder, practically insoluble in water, soluble in solutions of alkali hydroxides.

mp: about 185 °C.

Loss on drying (*2.2.32*): maximum 10.0 per cent, determined on 1.000 g.

Aminomethylalizarindiacetic acid reagent. *1003901.*

Solution A. Dissolve 0.36 g of *cerous nitrate R* in *water R* and dilute to 50 mL with the same solvent.

Solution B. Suspend 0.7 g of *aminomethylalizarindiacetic acid R* in 50 mL of *water R*. Dissolve with the aid of about 0.25 mL of *concentrated ammonia R*, add 0.25 mL of *glacial acetic acid R* and dilute to 100 mL with *water R*.

Solution C. Dissolve 6 g of *sodium acetate R* in 50 mL of *water R*, add 11.5 mL of *glacial acetic acid R* and dilute to 100 mL with *water R*.

To 33 mL of *acetone R* add 6.8 mL of solution C, 1.0 mL of solution B and 1.0 mL of solution A and dilute to 50 mL with *water R*.

Test for sensitivity. To 1.0 mL of *fluoride standard solution (10 ppm F) R* add 19.0 mL of *water R* and 5.0 mL of the aminomethylalizarindiacetic acid reagent. After 20 min, the solution assumes a blue colour.

Storage: use within 5 days.

Aminomethylalizarindiacetic acid solution. *1003902.*

Dissolve 0.192 g of *aminomethylalizarindiacetic acid R* in 6 mL of freshly prepared *1 M sodium hydroxide*. Add 750 mL of *water R*, 25 mL of *succinate buffer solution pH 4.6 R* and, dropwise, *0.5 M hydrochloric acid* until the colour changes from violet-red to yellow (pH 4.5 to 5). Add 100 mL of *acetone R* and dilute to 1000 mL with *water R*.

4-Aminomethylbenzoic acid. $C_8H_9NO_2$. (M_r 151.2). *1167800.* [56-91-7].

Aminonitrobenzophenone. $C_{13}H_{10}N_2O_3$. (M_r 242.2). *1004000.* [1775-95-7]. 2-Amino-5-nitrobenzophenone.

Yellow, crystalline powder, practically insoluble in water, soluble in tetrahydrofuran, slightly soluble in methanol.

mp: about 160 °C.

$A_{1\,cm}^{1\%}$: 690 to 720, determined at 233 nm using a 0.01 g/L solution in *methanol R*.

6-Aminopenicillanic acid. $C_8H_{12}N_2O_3S$. (M_r 216.3). *1162100.* [551-16-6]. (2*S*,5*R*,6*R*)-6-Amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.

Appearance: white or almost white powder.

mp: about 205 °C, with decomposition.

Aminophenazone. $C_{13}H_{17}N_3O$. (231.3). *1133900.* [58-15-1]. 4-(Dimethylamino)-1,5-dimethyl-2-phenyl-1,2-dihydro-3*H*-pyrazol-3-one.

White or almost white, crystalline powder or colourless crystals, soluble in water, freely soluble in ethanol (96 per cent).

mp: about 108 °C.

2-Aminophenol. C_6H_7NO. (M_r 109.1). *1147500.* [95-55-6].

Pale yellowish-brown crystals which rapidly become brown, sparingly soluble in water, soluble in ethanol (96 per cent).

mp: about 172 °C.

Storage: in an airtight container, protected from light.

3-Aminophenol. C_6H_7NO. (M_r 109.1). *1147600.* [591-27-5].

Pale yellowish-brown crystals, sparingly soluble in water.

mp: about 122 °C.

4-Aminophenol. C_6H_7NO. (M_r 109.1). *1004300.* [123-30-8].

Content: minimum 95 per cent.

White or slightly coloured, crystalline powder, becoming coloured on exposure to air and light, sparingly soluble in water, soluble in anhydrous ethanol.

mp: about 186 °C, with decomposition.

Storage: protected from light.

Aminopolyether. $C_{18}H_{36}N_2O_6$. (M_r 376.5). *1112500.* [23978-09-8]. 4,7,13,16,21,24-hexaoxa-1,10-diazabicyclo[8,8,8]hexacosane.

mp: 70 °C to 73 °C.

3-Aminopropanol. C_3H_9NO. (M_r 75.1). *1004400.* [156-87-6]. 3-Aminopropan-1-ol. Propanolamine.

Clear, colourless, viscous liquid.

d_{20}^{20}: about 0.99.

n_D^{20}: about 1.461.

mp: about 11 °C.

3-Aminopropionic acid. $C_3H_7NO_2$. (M_r 89.1). *1004500.* [107-95-9]. β-Alanine.

Content: minimum 99 per cent.

White or almost white, crystalline powder, freely soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in acetone.

mp: about 200 °C, with decomposition.

Aminopyrazolone. $C_{11}H_{13}N_3O$. (M_r 203.2). *1004600.* [83-07-8]. 4-Amino-2,3-dimethyl-1-phenylpyrazolin-5-one.

Light-yellow needles or powder, sparingly soluble in water, freely soluble in ethanol (96 per cent).

mp: about 108 °C.

Aminopyrazolone solution. *1004601.*

A 1 g/L solution in *buffer solution pH 9.0 R*.

Ammonia, concentrated. *1004700.*

See *Concentrated ammonia solution (0877).*

Ammonia. *1004701.*

Content: 170 g/L to 180 g/L of NH_3 (M_r 17.03).

Dilute 67 g of *concentrated ammonia R* to 100 mL with *water R*.

d_{20}^{20}: 0.931 to 0.934.

When used in the test for iron, *ammonia R* complies with the following additional requirement. Evaporate 5 mL of ammonia to dryness on a water-bath, add 10 mL of *water R*,

2 mL of a 200 g/L solution of *citric acid R* and 0.1 mL of *thioglycollic acid R*. Make alkaline by adding *ammonia R* and dilute to 20 mL with *water R*. No pink colour develops.

Storage: protected from atmospheric carbon dioxide, at a temperature below 20 °C.

Ammonia, dilute R1. *1004702.*

Content: 100 g/L to 104 g/L of NH_3 (M_r 17.03).

Dilute 41 g of *concentrated ammonia R* to 100 mL with *water R*.

Ammonia, dilute R2. *1004703.*

Content: 33 g/L to 35 g/L of NH_3 (M_r 17.03).

Dilute 14 g of *concentrated ammonia R* to 100 mL with *water R*.

Ammonia, dilute R3. *1004704.*

Content: 1.6 g/L to 1.8 g/L of NH_3 (M_r 17.03).

Dilute 0.7 g of *concentrated ammonia R* to 100 mL with *water R*.

Ammonia, dilute R4. *1004706.*

Content: 8.4 g/L to 8.6 g/L of NH_3 (M_r 17.03).

Dilute 3.5 g of *concentrated ammonia R* to 100 mL with *water R*.

Ammonia, lead-free. *1004705.*

Complies with the requirements prescribed for *dilute ammonia R1* with the following additional test: to 20 mL of lead-free ammonia, add 1 mL of *lead-free potassium cyanide solution R*, dilute to 50 mL with *water R* and add 0.10 mL of *sodium sulfide solution R*. The solution is not more intensely coloured than a reference solution prepared without sodium sulfide.

Ammonia, concentrated R1. *1004800.*

Content: minimum 32.0 per cent *m/m* of NH_3 (M_r 17.03).

A clear, colourless liquid.

d_{20}^{20}: 0.883 to 0.889.

Assay. Weigh accurately a ground-glass-stoppered flask containing 50.0 mL of *1 M hydrochloric acid*. Introduce 2 mL of the concentrated ammonia and weigh again. Titrate the solution with *1 M sodium hydroxide*, using 0.5 mL of *methyl red mixed solution R* as indicator.

1 mL of *1 M hydrochloric acid* is equivalent to 17.03 mg of NH_3.

Storage: protected from atmospheric carbon dioxide, at a temperature below 20 °C.

Ammonium acetate. $C_2H_7NO_2$. (M_r 77.1). *1004900.* [631-61-8].

Colourless crystals, very deliquescent, very soluble in water and in ethanol (96 per cent).

Storage: in an airtight container.

Ammonium acetate solution. *1004901.*

Dissolve 150 g of *ammonium acetate R* in *water R*. Add 3 mL of *glacial acetic acid R* and dilute to 1000 mL with *water R*.

Storage: use within 1 week.

Ammonium and cerium nitrate. $(NH_4)_2Ce(NO_3)_6$. (M_r 548.2). *1005000.* [16774-21-3].

Orange-yellow, crystalline powder, or orange transparent crystals, soluble in water.

Ammonium and cerium sulfate. $(NH_4)_4Ce(SO_4)_4,2H_2O$. (M_r 633). *1005100.* [10378-47-9].

Orange-yellow, crystalline powder or crystals, slowly soluble in water.

(1*R*)-(−)-Ammonium 10-camphorsulfonate. $C_{10}H_{19}NO_4S$. (M_r 249.3). *1103200.*

Content: minimum 97.0 per cent of (1*R*)-(−)-ammonium 10-camphorsulfonate.

$[\alpha]_D^{20}$: − 18 ± 2, determined on a 50 g/L solution.

Ammonium carbamate. $CH_6N_2O_2$. (M_r 78.1). *1168400.* [1111-78-0]. Carbamic acid ammonium salt.

Ammonium carbonate. *1005200.* [506-87-6]. A mixture of varying proportions of ammonium hydrogen carbonate (NH_4HCO_3, M_r 79.1) and ammonium carbamate (NH_2COONH_4, M_r 78.1).

White or almost white translucent mass, slowly soluble in about 4 parts of water. It is decomposed by boiling water. Ammonium carbonate liberates not less than 30 per cent *m/m* of NH_3 (M_r 17.03).

Assay. Dissolve 2.00 g in 25 mL of *water R*. Slowly add 50.0 mL of *1 M hydrochloric acid*, titrate with *1 M sodium hydroxide*, using 0.1 mL of *methyl orange solution R* as indicator.

1 mL of *1 M hydrochloric acid* is equivalent to 17.03 mg of NH_3.

Storage: at a temperature below 20 °C.

Ammonium carbonate solution. *1005201.*

A 158 g/L solution.

Ammonium carbonate solution R1. *1005202.*

Dissolve 20 g of *ammonium carbonate R* in 20 mL of *dilute ammonia R1* and dilute to 100 mL with *water R*.

Ammonium chloride. *1005300.* [12125-02-9].

See *Ammonium chloride (0007)*.

Ammonium chloride solution. *1005301.*

A 107 g/L solution.

Ammonium citrate. $C_6H_{14}N_2O_7$. (M_r 226.2). *1103300.* [3012-65-5]. Diammonium hydrogen citrate.

White or almost white, crystalline powder or colourless crystals, freely soluble in water, slightly soluble in ethanol (96 per cent).

pH (*2.2.3*): about 4.3 for a 22.6 g/L solution.

Ammonium dihydrogen phosphate. $(NH_4)H_2PO_4$. (M_r 115.0). *1005400.* [7722-76-1]. Monobasic ammonium phosphate.

White or almost white, crystalline powder or colourless crystals, freely soluble in water.

pH (*2.2.3*): about 4.2 for a 23 g/L solution.

Ammonium formate. CH_5NO_2. (M_r 63.1). *1112600.* [540-69-2].

Deliquescent crystals or granules, very soluble in water, soluble in ethanol (96 per cent).

mp: 119 °C to 121 °C.

Storage: in an airtight container.

Ammonium hexafluorogermanate(IV). $(NH_4)_2GeF_6$. (M_r 222.7). *1134000.* [16962-47-3].

White or almost white crystals, freely soluble in water.

Ammonium hydrogen carbonate. NH_4HCO_3. (M_r 79.1). *1005500.* [1066-33-7].

Content: minimum 99 per cent.

Ammonium molybdate. $(NH_4)_6Mo_7O_{24},4H_2O$. (M_r 1236). *1005700.* [12054-85-2].

Colourless or slightly yellow or greenish crystals, soluble in water, practically insoluble in ethanol (96 per cent).

Ammonium molybdate reagent. *1005701.*

Mix, in the given order, 1 volume of a 25 g/L solution of *ammonium molybdate R*, 1 volume of a 100 g/L solution of *ascorbic acid R* and 1 volume of *sulfuric acid R* (294.5 g/L H_2SO_4). Add 2 volumes of *water R*.

Storage: use within 1 day.

Ammonium molybdate reagent R1. *1005706.*

Mix 10 mL of a 60 g/L solution of *disodium arsenate R*, 50 mL of *ammonium molybdate solution R*, 90 mL of *dilute sulfuric acid R* and dilute to 200 mL in *water R*.

Storage: in amber flasks at 37 °C for 24 h.

Ammonium molybdate reagent R2. *1005708.*

Dissolve 50 g of *ammonium molybdate R* in 600 mL of *water R*. To 250 mL of cold *water R* add 150 mL of *sulfuric acid R* and cool. Mix the 2 solutions together. *Storage*: use within 1 day.

Ammonium molybdate solution. *1005702.*

A 100 g/L solution.

Ammonium molybdate solution R2. *1005703.*

Dissolve 5.0 g of *ammonium molybdate R* with heating in 30 mL of *water R*. Cool, adjust the pH to 7.0 with *dilute ammonia R2* and dilute to 50 mL with *water R*.

Ammonium molybdate solution R3. *1005704.*

Solution A. Dissolve 5 g of *ammonium molybdate R* in 20 mL of *water R* with heating.

Solution B. Mix 150 mL of *ethanol (96 per cent) R* with 150 mL of *water R*. Add with cooling 100 mL of *sulfuric acid R*.

Immediately before use add 80 volumes of solution B to 20 volumes of solution A.

Ammonium molybdate solution R4. *1005705.*

Dissolve 1.0 g of *ammonium molybdate R* in *water R* and dilute to 40 mL with the same solvent. Add 3 mL of *hydrochloric acid R* and 5 mL of *perchloric acid R* and dilute to 100 mL with *acetone R*.

Storage: protected from light; use within 1 month.

Ammonium molybdate solution R5. *1005707.*

Dissolve 1.0 g of *ammonium molybdate R* in 40.0 mL of a 15 per cent *V/V* solution of *sulfuric acid R*. Prepare the solution daily.

Ammonium molybdate solution R6. *1005709.*

Slowly add 10 mL of *sulfuric acid R* to about 40 mL of *water R*. Mix and allow to cool. Dilute to 100 mL with *water R* and mix. Add 2.5 g of *ammonium molybdate R* and 1 g of *cerium sulfate R*, and shake for 15 min to dissolve.

Ammonium nitrate. NH_4NO_3. (M_r 80.0). *1005800.* [6484-52-2].

White or almost white, crystalline powder or colourless crystals, hygroscopic, very soluble in water, freely soluble in methanol, soluble in ethanol (96 per cent).

Storage: in an airtight container.

Ammonium nitrate R1. *1005801.*

Complies with the requirements prescribed for *ammonium nitrate R* with the following additional requirements.

Acidity. The solution of the substance is slightly acid (*2.2.4*).

Chlorides (*2.4.4*): maximum 100 ppm, determined on 0.50 g.

Sulfates (*2.4.13*): maximum 150 ppm, determined on 1.0 g.

Sulfated ash (*2.4.14*): maximum 0.05 per cent, determined on 1.0 g.

Ammonium oxalate. $C_2H_8N_2O_4,H_2O$. (M_r 142.1). *1005900.* [6009-70-7].

Colourless crystals, soluble in water.

Ammonium oxalate solution. *1005901.*

A 40 g/L solution.

Ammonium persulfate. $(NH_4)_2S_2O_8$. (M_r 228.2). *1006000.* [7727-54-0].

White or almost white, crystalline powder or granular crystals, freely soluble in water.

Ammonium phosphate. $(NH_4)_2HPO_4$. (M_r 132.1). *1006100.* [7783-28-0]. Diammonium hydrogen phosphate.

White or almost white crystals or granules, hygroscopic, very soluble in water, practically insoluble in ethanol (96 per cent).

pH (*2.2.3*): about 8 for a 200 g/L solution.

Storage: in an airtight container.

Ammonium pyrrolidinedithiocarbamate. $C_5H_{12}N_2S_2$. (M_r 164.3). *1006200.* [5108-96-3]. Ammonium 1-pyrrolidinyl-dithioformate.

White or pale yellow, crystalline powder, sparingly soluble in water, very slightly soluble in ethanol (96 per cent).

Storage: in a bottle containing a piece of ammonium carbonate in a muslin bag.

Ammonium reineckate. $NH_4[Cr(NCS)_4(NH_3)_2],H_2O$. ($M_r$ 354.4). *1006300.* [13573-16-5]. Ammonium diamine-tetrakis(isothiocyanato)chromate(III) monohydrate.

Red powder or crystals, sparingly soluble in cold water, soluble in hot water and in ethanol (96 per cent).

Ammonium reineckate solution. *1006301.*

A 10 g/L solution. Prepare immediately before use.

Ammonium sulfamate. $NH_2SO_3NH_4$. (M_r 114.1). *1006400.* [7773-06-0].

White or almost white, crystalline powder or colourless crystals, hygroscopic, very soluble in water, slightly soluble in ethanol (96 per cent).

mp: about 130 °C.

Storage: in an airtight container.

Ammonium sulfate. $(NH_4)_2SO_4$. (M_r 132.1). *1006500.* [7783-20-2].

Colourless crystals or white or almost white granules, very soluble in water, practically insoluble in acetone and in ethanol (96 per cent).

pH (*2.2.3*): 4.5 to 6.0 for a 50 g/L solution in *carbon dioxide-free water R*.

Sulfated ash (*2.4.14*): maximum 0.1 per cent.

Ammonium sulfide solution. *1123300.*

Saturate 120 mL of *dilute ammonia R1* with *hydrogen sulfide R* and add 80 mL of *dilute ammonia R1*. Prepare immediately before use.

Ammonium thiocyanate. NH_4SCN. (M_r 76.1). *1006700.* [1762-95-4].

Colourless crystals, deliquescent, very soluble in water, soluble in ethanol (96 per cent).

Storage: in an airtight container.

Ammonium thiocyanate solution. *1006701.*

A 76 g/L solution.

Ammonium vanadate. NH_4VO_3. (M_r 117.0). *1006800.* [7803-55-6]. Ammonium trioxovanadate(V).

White or slightly yellowish, crystalline powder, slightly soluble in water, soluble in *dilute ammonia R1*.

Ammonium vanadate solution. *1006801.*

Dissolve 1.2 g of *ammonium vanadate R* in 95 mL of *water R* and dilute to 100 mL with *sulfuric acid R*.

Amoxicillin trihydrate. *1103400.*

See *Amoxicillin trihydrate (0260)*.

α-Amylase. *1100800.* 1,4-α-D-glucane-glucanohydrolase (EC *3.2.1.1*).

White or light brown powder.

α-Amylase solution. *1100801.*

A solution of *α-amylase R* with an activity of 800 FAU/g.

β-Amyrin. $C_{30}H_{50}O$. (M_r 426.7). *1141800.* [559-70-6]. Olean-12-en-3β-ol.

White or almost white powder.

mp: 187 °C to 190 °C.

Anethole. $C_{10}H_{12}O$. (M_r 148.2). *1006900.* [4180-23-8]. 1-Methoxy-4-(propen-1-yl)benzene.

White or almost white, crystalline mass up to 20 °C to 21 °C, liquid above 23 °C, practically insoluble in water, freely soluble in anhydrous ethanol, soluble in ethyl acetate and in light petroleum.

n_D^{25}: about 1.56.

bp: about 230 °C.

Anethole used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Anise oil (0804).*

Test solution. The substance to be examined.

Content: minimum 99.0 per cent of *trans*-anethole (retention time: about 41 min), calculated by the normalisation procedure.

Aniline. C_6H_7N. (M_r 93.1). *1007100.* [62-53-3]. Benzeneamine.

Colourless or slightly yellowish liquid, soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 1.02.

bp: 183 °C to 186 °C.

Storage: protected from light.

Aniline hydrochloride. C_6H_8ClN. (M_r 129.6). *1147700.* [142-04-1]. Benzenamine hydrochloride.

Crystals. It darkens on exposure to air and light.

mp: about 198 °C.

Storage: protected from light.

Anion exchange resin. *1007200.*

Resin in chlorinated form containing quaternary ammonium groups [$CH_2N^+(CH_3)_3$] attached to a polymer lattice consisting of polystyrene cross-linked with 2 per cent of divinylbenzene. It is available as spherical beads and the particle size is specified in the monograph.

Wash the resin with *1 M sodium hydroxide* on a sintered-glass filter (40) (*2.1.2*) until the washings are free from chloride, then wash with *water R* until the washings are neutral. Suspend in freshly prepared *ammonium-free water R* and protect from atmospheric carbon dioxide.

Anion exchange resin R1. *1123400.*

Resin containing quaternary ammonium groups [$CH_2N^+(CH_3)_3$] attached to a lattice consisting of methacrylate.

Anion exchange resin R2. *1141900.*

Conjugate of homogeneous 10 µm hydrophilic polyether particles, and a quaternary ammonium salt, providing a matrix suitable for strong anion-exchange chromatography of proteins.

Anion exchange resin for chromatography, strongly basic. *1112700.*

Resin with quaternary amine groups attached to a lattice of latex cross linked with divinylbenzene.

Anion exchange resin, strongly basic. *1026600.*

Gel-type resin in hydroxide form containing quaternary ammonium groups [$CH_2N^+(CH_3)_3$, type 1] attached to a polymer lattice consisting of polystyrene cross-linked with 8 per cent of divinylbenzene.

Brown transparent beads.

Particle size: 0.2 mm to 1.0 mm.

Moisture content: about 50 per cent.

Total exchange capacity: minimum 1.2 meq/mL.

Anion exchange resin, weak. *1146700.*

Resin with diethylaminoethyl groups attached to a lattice consisting of poly(methyl methacrylate).

Anisaldehyde. $C_8H_8O_2$. (M_r 136.1). *1007300.* [123-11-5]. 4-Methoxybenzaldehyde.

Oily liquid, very slightly soluble in water, miscible with ethanol (96 per cent).

bp: about 248 °C.

Anisaldehyde used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Anise oil (0804).*

Test solution. The substance to be examined.

Content: minimum 99.0 per cent, calculated by the normalisation procedure.

Anisaldehyde solution. *1007301.*

Mix in the following order, 0.5 mL of *anisaldehyde R*, 10 mL of *glacial acetic acid R*, 85 mL of *methanol R* and 5 mL of *sulfuric acid R*.

Anisaldehyde solution R1. *1007302.*

To 10 mL of *anisaldehyde R* add 90 mL of *ethanol (96 per cent) R*, mix, add 10 mL of *sulfuric acid R* and mix again.

Anise ketone. $C_{10}H_{12}O_2$. (M_r 164.2). *1174700.* [122-84-9]. 1-(4-Methoxyphenyl)propan-2-one.

***p*-Anisidine.** C_7H_9NO. (M_r 123.2). *1103500.* [104-94-9]. 4-Methoxyaniline.

White or almost white crystals, sparingly soluble in water, soluble in anhydrous ethanol.

Content: minimum 97.0 per cent.

Caution: skin irritant, sensitiser.

Storage: protected from light, at 0 °C to 4 °C.

On storage, *p*-anisidine tends to darken as a result of oxidation. A discoloured reagent can be reduced and decolorised in the following way: dissolve 20 g of *p-anisidine R* in 500 mL of *water R* at 75 °C. Add 1 g of *sodium sulfite R* and 10 g of *activated charcoal R* and stir for 5 min. Filter, cool the filtrate to about 0 °C and allow to stand at this temperature for at least 4 h. Filter, wash the crystals with a small quantity of *water R* at about 0 °C and dry the crystals in vacuum over *diphosphorus pentoxide R*.

Anthracene. $C_{14}H_{10}$. (M_r 178.2). *1007400.* [120-12-7].

White or almost white, crystalline powder, practically insoluble in water, slightly soluble in chloroform.

mp: about 218 °C.

Anthrone. $C_{14}H_{10}O$. (M_r 194.2). *1007500.* [90-44-8]. 9(10*H*)-Anthracenone.

Pale yellow, crystalline powder.

mp: about 155 °C.

Antimony potassium tartrate. $C_4H_4KO_7Sb,{}^1/_2H_2O$. (M_r 333.9). *1007600.* Potassium aqua[tartrato(4−)-O^1,O^2,O^3]-antimoniate(III) hemihydrate.

White or almost white, granular powder or colourless, transparent crystals, soluble in water and in glycerol, freely soluble in boiling water, practically insoluble in ethanol (96 per cent). The aqueous solution is slightly acid.

Antimony trichloride. $SbCl_3$. (M_r 228.1). *1007700.* [10025-91-9].

Colourless crystals or a transparent crystalline mass, hygroscopic, freely soluble in anhydrous ethanol. Antimony trichloride is hydrolysed by water.

Storage: in an airtight container, protected from moisture.

Antimony trichloride solution. *1007701.*

Rapidly wash 30 g of *antimony trichloride R* with two quantities, each of 15 mL, of *ethanol-free chloroform R*, drain off the washings, and dissolve the washed crystals immediately in 100 mL of *ethanol-free chloroform R*, warming slightly.

Storage: over a few grams of *anhydrous sodium sulfate R*.

Antimony trichloride solution R1. *1007702.*

Solution A. Dissolve 110 g of *antimony trichloride R* in 400 mL of *ethylene chloride R*. Add 2 g of *anhydrous aluminium oxide R*, mix and filter through a sintered-glass filter (40) (*2.1.2*). Dilute to 500.0 mL with *ethylene chloride R* and mix. The absorbance (*2.2.25*) of the solution, determined at 500 nm in a 2 cm cell, is not greater than 0.07.

Solution B. Under a hood, mix 100 mL of freshly distilled *acetyl chloride R* and 400 mL of *ethylene chloride R*.

Mix 90 mL of solution A and 10 mL of solution B.

Storage: in brown ground-glass-stoppered bottle for 7 days. Discard any reagent in which colour develops.

Antithrombin III. *1007800.* [90170-80-2].

Antithrombin III is purified from human plasma by heparin agarose chromatography and should have a specific activity of at least 6 IU/mg.

Antithrombin III solution R1. *1007801.*

Reconstitute *antithrombin III R* as directed by the manufacturer and dilute with *tris(hydroxymethyl)aminomethane sodium chloride buffer solution pH 7.4 R* to 1 IU/mL.

Antithrombin III solution R2. *1007802.*

Reconstitute *antithrombin III R* as directed by the manufacturer and dilute with *tris(hydroxymethyl)aminomethane sodium chloride buffer solution pH 7.4 R* to 0.5 IU/mL.

Antithrombin III solution R3. *1007803.*

Reconstitute *antithrombin III R* as directed by the manufacturer and dilute to 0.3 IU/mL with *phosphate buffer solution pH 6.5 R*.

Antithrombin III solution R4. *1007804.*

Reconstitute *antithrombin III R* as directed by the manufacturer and dilute to 0.1 IU/mL with *tris(hydroxymethyl)aminomethane EDTA buffer solution pH 8.4 R*.

Apigenin. $C_{15}H_{10}O_5$. (M_r 270.2). *1095800.* [520-36-5]. 4′,5,7-Trihydroxyflavone.

Light yellowish powder, practically insoluble in water, sparingly soluble in ethanol (96 per cent).

mp: about 310 °C, with decomposition.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Roman chamomile flower (0380)*: apply 10 µL of a 0.25 g/L solution in *methanol R*; the chromatogram shows in the upper third a principal zone of yellowish-green fluorescence.

Apigenin 7-glucoside. $C_{21}H_{20}O_{10}$. (M_r 432.4). *1095900.* [578-74-5]. Apigetrin. 7-(β-D-Glucopyranosyloxy)-5-hydroxy-2-(4-hydroxyphenyl)-4*H*-1-benzopyran-4-one.

Light yellowish powder, practically insoluble in water, sparingly soluble in ethanol (96 per cent).

mp: 198 °C to 201 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Roman chamomile flower (0380)*: apply 10 µL of a 0.25 g/L solution in *methanol R*; the chromatogram shows in the middle third a principal zone of yellowish fluorescence.

Apigenin-7-glucoside used in liquid chromatography complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Matricaria flower (0404)*.

Test solution. Dissolve 10.0 mg in *methanol R* and dilute to 100.0 mL with the same solvent.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Aprotinin. *1007900.* [9087-70-1].

See *Aprotinin (0580)*.

Arabinose. $C_5H_{10}O_5$. (M_r 150.1). *1008000.* [87-72-9]. L-(+)-Arabinose.

White or almost white, crystalline powder, freely soluble in water.

$[\alpha]_D^{20}$: + 103 to + 105, determined on a 50 g/L solution in *water R* containing about 0.05 per cent of NH_3.

Arachidyl alcohol. $C_{20}H_{42}O$. (M_r 298.5). *1156300.* [629-96-9]. 1-Eicosanol.

mp: about 65 °C.

Content: minimum 96 per cent of $C_{20}H_{42}O$.

Arbutin. $C_{12}H_{16}O_7$. (M_r 272.3). *1008100.* [497-76-7]. Arbutoside. 4-Hydroxyphenyl-β-D-glucopyranoside.

Fine, white or almost white, shiny needles, freely soluble in water, very soluble in hot water, soluble in ethanol (96 per cent).

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Bearberry leaf (1054)*; the chromatogram shows only one principal spot.

Arginine. *1103600.* [74-79-3].

See *Arginine (0806)*.

Argon. Ar. (A_r 39.95). *1008200.* [7440-37-1].

Content: minimum 99.995 per cent *V/V*.

Carbon monoxide (*2.5.25, Method I*): maximum 0.6 ppm *V/V*; after passage of 10 L of *argon R* at a flow rate of 4 L/h, not more than 0.05 mL of *0.002 M sodium thiosulfate* is required for the titration.

Argon R1. Ar. (A_r 39.95). *1176000.* [7440-37-1].

Content: minimum 99.99990 per cent *V/V*.

Argon for chromatography. Ar. (A_r 39.95). *1166200.* [7440-37-1].

Content: minimum 99.95 per cent *V/V*.

Aromadendrene. $C_{15}H_{24}$. (M_r 204.4). *1139100.* [489-39-4]. (1*R*,2*S*,4*R*,8*R*,11*R*)-3,3,11-Trimethyl-7-methylenetricyclo-[6.3.0.0^{2,4}]undecane.

Clear, almost colourless liquid.

d_4^{20}: about 0.911.

n_D^{20}: about 1.497.

$[\alpha]_D^{20}$: about + 12.

bp: about 263 °C.

Aromadendrene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph on *Tea tree oil (1837)*.

Content: minimum 92 per cent, calculated by the normalisation procedure.

Arsenious trioxide. As_2O_3. (M_r 197.8). *1008300.* [1327-53-3]. Arsenious anhydride. Diarsenic trioxide.

Crystalline powder or a white or almost white mass, slightly soluble in water, soluble in boiling water.

Arsenite solution. *1008301.*

Dissolve 0.50 g of *arsenious trioxide R* in 5 mL of *dilute sodium hydroxide solution R*, add 2.0 g of *sodium hydrogen carbonate R* and dilute to 100.0 mL with *water R*.

Ascorbic acid. *1008400.* [50-81-7].

See *Ascorbic acid (0253)*.

Ascorbic acid solution. *1008401.*

Dissolve 50 mg in 0.5 mL of *water R* and dilute to 50 mL with *dimethylformamide R*.

Asiaticoside. $C_{48}H_{78}O_{19}$. (M_r 959). *1123500.* [16830-15-2]. *O*-6-Deoxy-α-L-mannopyranosyl-(1→4)-*O*-β-D-glucopyranosyl-(1→6)-β-D-glucopyranosyl 2α,3β,23-trihydroxy-4α-urs-12-en-28-oate.

White or almost white powder, hygroscopic, soluble in methanol, slightly soluble in anhydrous ethanol, insoluble in acetonitrile.

mp: about 232 °C, with decomposition.

Water (*2.5.12*): 6.0 per cent.

Asiaticoside used in liquid chromatography complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Centella (1498)*.

Content: minimum 97.0 per cent, calculated by the normalisation procedure.

Storage: protected from humidity.

Aspartic acid. *1134100.* [56-84-8].

See *Aspartic acid (0797)*.

L-Aspartyl-L-phenylalanine. $C_{13}H_{16}N_2O_5$. (M_r 280.3). *1008500.* [13433-09-5]. (*S*)-3-Amino-*N*-[(*S*)-1-carboxy-2-phenylethyl]-succinamic acid.

White or almost white powder.

mp: about 210 °C, with decomposition.

Astragaloside IV. $C_{41}H_{68}O_{14}$. (M_r 785). *1178200.* [84687-43-4]. (20*R*,24*S*)-20,24-Epoxy-16β,25-dihydroxy-3β-(β-D-xylopyranosyloxy)-9,19-cyclolanostan-6α-yl β-D-glucopyranoside.

Atropine sulfate. *1159000.* [5908-99-6].

See *Atropine sulfate (0068)*.

Aucubin. $C_{15}H_{22}O_9$. (M_r 346.3). *1145200.* [479-98-1]. [1*S*,4a*R*,5*S*,7a*S*)-5-Hydroxy-7-(hydroxymethyl)-1,4a,5,7a-tetrahydrocyclopenta[*c*]pyran-1-yl β-D-glucopyranoside.

Crystals, soluble in water, in ethanol (96 per cent) and in methanol, practically insoluble in light petroleum.

$[\alpha]_D^{20}$: about – 163.

mp: about 181 °C.

Azomethine H. $C_{17}H_{12}NNaO_8S_2$. (M_r 445.4). *1008700.* [5941-07-1]. Sodium hydrogeno-4-hydroxy-5-(2-hydroxybenzylideneamino)-2,7-naphthalenedisulfonate.

Azomethine H solution. *1008701.*

Dissolve 0.45 g of *azomethine H R* and 1 g of *ascorbic acid R* with gentle heating in *water R* and dilute to 100 mL with the same solvent.

Barbaloin. $C_{21}H_{22}O_9,H_2O$. (M_r 436.4). *1008800.* [1415-73-2]. Aloin. 1,8-Dihydroxy-3-hydroxymethyl-10-β-D-glucopyranosyl-10*H*-anthracen-9-one.

Yellow to dark-yellow, crystalline powder, or yellow needles, darkening on exposure to air and light, sparingly soluble in water and in ethanol (96 per cent), soluble in acetone, in ammonia and in solutions of alkali hydroxides.

$A_{1\,cm}^{1\%}$: about 192 at 269 nm, about 226 at 296.5 nm, about 259 at 354 nm, determined on a solution in *methanol R* and calculated with reference to the anhydrous substance.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Frangula bark (0025)*; the chromatogram shows only one principal spot.

Barbital. *1008900.* [57-44-3].

See *Barbital (0170)*.

Barbital sodium. $C_8H_{11}N_2NaO_3$. (M_r 206.2). *1009000.* [144-02-5]. Sodium derivative of 5,5-diethyl-1*H*,3*H*,5*H*-pyrimidine-2,4,6-trione.

Content: minimum 98.0 per cent.

A white or almost white, crystalline powder or colourless crystals, freely soluble in water, slightly soluble in ethanol (96 per cent).

Barbituric acid. $C_4H_4N_2O_3$. (M_r 128.1). *1009100.* [67-52-7]. 1*H*,3*H*,5*H*-Pyrimidine-2,4,6-trione.

White or almost white powder, slightly soluble in water, freely soluble in boiling water and in dilute acids.

mp: about 253 °C.

Barium acetate. $C_4H_6BaO_4$. (M_r 255.4). *1162700.* [543-80-6]. Barium diacetate.

White or almost white powder, soluble in water.

d_{20}^{20}: 2.47.

Barium carbonate. $BaCO_3$. (M_r 197.3). *1009200.* [513-77-9].

White or almost white powder or friable masses, practically insoluble in water.

Barium chloride. $BaCl_2,2H_2O$. (M_r 244.3). *1009300.* [10326-27-9]. Barium dichloride.

Colourless crystals, freely soluble in water, slightly soluble in ethanol (96 per cent).

Barium chloride solution R1. *1009301.*

A 61 g/L solution.

Barium chloride solution R2. *1009302.*

A 36.5 g/L solution.

Barium hydroxide. $Ba(OH)_2,8H_2O$. (M_r 315.5). *1009400.* [12230-71-6]. Barium dihydroxide.

Colourless crystals, soluble in water.

Barium hydroxide solution. *1009401.*

A 47.3 g/L solution.

Barium nitrate. $Ba(NO_3)_2$. (M_r 261.3). *1163800.* [10022-31-8].

Crystals or crystalline powder, freely soluble in water, very slightly soluble in ethanol (96 per cent) and in acetone.

mp: about 590 °C.

Barium sulfate. *1009500.* [7727-43-7].

See *Barium sulfate (0010)*.

Benzalacetone. $C_{10}H_{10}O$. (M_r 146.2). *1168500.* [122-57-6]. (3*E*)-4-phenylbut-3-en-2-one.

White or pale yellow mass.

Content: minimum 98.0 per cent.

bp: about 261 °C.

mp: about 39 °C.

Benzaldehyde. C_7H_6O. (M_r 106.1). *1009600.* [100-52-7].

Colourless or slightly yellow liquid, slightly soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 1.05.

n_D^{20}: about 1.545.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 177 °C and 180 °C.

Storage: protected from light.

Benzene. C_6H_6. (M_r 78.1). *1009800.* [71-43-2].

Clear, colourless, flammable liquid, practically insoluble in water, miscible with ethanol (96 per cent).

bp: about 80 °C.

Benzene-1,2,4-triol. $C_6H_6O_3$. (M_r 126.1). *1177500.* [533-73-3]. Hydroxyhydroquinone. Hydroxyquinol.

Freely soluble in water, in ethanol (96 per cent) and in ethyl acetate.

mp: about 140 °C.

Benzethonium chloride. $C_{27}H_{42}ClNO_2,H_2O$. (M_r 466.1). *1009900.* [121-54-0]. Benzyldimethyl[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]ammonium chloride monohydrate.

Fine, white or almost white powder or colourless crystals, soluble in water and in ethanol (96 per cent).

mp: about 163 °C.

Storage: protected from light.

Benzidine. $C_{12}H_{12}N_2$. (M_r 184.2). *1145300.* [92-87-5]. Biphenyl-4,4′-diamine.

Content: minimum 95 per cent.

White or slightly yellowish or reddish powder, darkening on exposure to air and light.

mp: about 120 °C.

Storage: protected from light.

Benzil. $C_{14}H_{10}O_2$. (M_r 210.2). *1117800.* [134-81-6]. Diphenylethanedione.

Yellow, crystalline powder, practically insoluble in water, soluble in ethanol (96 per cent), ethyl acetate and toluene.

mp: 95 °C.

Benzocaine. $C_9H_{11}NO_2$. (M_r 165.2). *1123600.* [94-09-7].

See *Benzocaine (0011)*.

Benzoic acid. *1010100.* [65-85-0].

See *Benzoic acid (0066)*.

Benzoin. $C_{14}H_{12}O_2$. (M_r 212.3). *1010200.* [579-44-2]. 2-Hydroxy-1,2-diphenylethanone.

Slightly yellowish crystals, very slightly soluble in water, freely soluble in acetone, soluble in hot ethanol (96 per cent).

mp: about 137 °C.

Benzophenone. $C_{13}H_{10}O$. (M_r 182.2). *1010300.* [119-61-9]. Diphenylmethanone.

Prismatic crystals, practically insoluble in water, freely soluble in ethanol (96 per cent).

mp: about 48 °C.

1,4-Benzoquinone. $C_6H_4O_2$. (M_r 108.1). *1118500.* [106-51-4]. Cyclohexa-2,5-diene-1,4-dione.

Content: minimum 98.0 per cent.

Benzoylarginine ethyl ester hydrochloride. $C_{15}H_{23}ClN_4O_3$. (M_r 342.8). *1010500.* [2645-08-1]. *N*-Benzoyl-L-arginine ethyl ester hydrochloride. Ethyl (*S*)-2-benzamido-5-guanidinovalerate hydrochloride.

White or almost white, crystalline powder, very soluble in water and in anhydrous ethanol.

$[\alpha]_D^{20}$: – 15 to – 18, determined on a 10 g/L solution.

mp: about 129 °C.

$A_{1\,cm}^{1\%}$: 310 to 340, determined at 227 nm using a 0.01 g/L solution.

Benzoyl chloride. C_7H_5ClO. (M_r 140.6). *1010400.* [98-88-4].

Colourless, lachrymatory liquid, decomposed by water and by ethanol (96 per cent).

d_{20}^{20}: about 1.21.

bp: about 197 °C.

***N*-Benzoyl-L-prolyl-L-phenylalanyl-L-arginine 4-nitroanilide acetate.** $C_{35}H_{42}N_8O_8$. (M_r 703). *1010600.*

3-Benzoylpropionic acid. $C_{10}H_{10}O_3$. (M_r 178.2). *1171000.* [2051-95-8]. 4-Oxo-4-phenylbutanoic acid.

mp: about 118 °C.

2-Benzoylpyridine. $C_{12}H_9NO$. (M_r 183.2). *1134300.* [91-02-1]. Phenyl(pyridin-2-yl)methanone.

Colourless crystals, soluble in ethanol (96 per cent).

mp: about 43 °C.

Benzyl alcohol. *1010700.* [100-51-6].

See *Benzyl alcohol (0256)*.

Benzyl benzoate. *1010800.* [120-51-4].

See *Benzyl benzoate (0705)*.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Peru balsam (0754)*: apply 20 µL of a 0.3 per cent *V/V* solution in *ethyl acetate R*; after spraying and heating, the chromatogram shows a principal band with an R_F of about 0.8.

Benzyl cinnamate. $C_{16}H_{14}O_2$. (M_r 238.3). *1010900.* [103-41-3]. Benzyl 3-phenylprop-2-enoate.

Colourless or yellowish crystals, practically insoluble in water, soluble in ethanol (96 per cent).

mp: about 39 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Peru balsam (0754)*: apply 20 µL of a 3 g/L solution in *ethyl acetate R*; after spraying and heating, the chromatogram shows a principal band with an R_F of about 0.6.

Benzyl cyanide. C_8H_7N. (M_r 117.2). *1171100.* [140-29-4]. Phenylacetonitrile.

Content: minimum 95.0 per cent.

Clear, colourless or light yellow liquid.

n_D^{20}: about 1.523.

bp: about 233 °C.

Benzyl ether. $C_{14}H_{14}O$. (M_r 198.3). *1140900.* [103-50-4]. Dibenzyl ether.

Clear, colourless liquid, practically insoluble in water, miscible with acetone and with anhydrous ethanol.

d_{20}^{20}: about 1.043.

n_D^{20}: about 1.562.

bp: about 296 °C, with decomposition.

Benzylpenicillin sodium. *1011000.* [69-57-8].

See *Benzylpenicillin sodium (0114)*.

2-Benzylpyridine. $C_{12}H_{11}N$. (M_r 169.2). *1112900.* [101-82-6].

Content: minimum 98.0 per cent.

Yellow liquid.

mp: 13 °C to 16 °C.

Benzyltrimethylammonium chloride. $C_{10}H_{16}ClN$. (M_r 185.7). *1155700.* [56-93-9]. *N,N,N*-Trimethylphenylmethanaminium chloride. *N,N,N*-Trimethylbenzenemethanaminium chloride.

White or almost white powder, soluble in water.

mp: about 230 °C, with decomposition.

Berberine chloride. $C_{20}H_{18}ClNO_4,2H_2O$. (M_r 407.8). *1153400.* [5956-60-5]. 9,10-Dimethoxy-5,6-dihydrobenzo[*g*]-1,3-benzodioxolo[5,6-*a*]quinolizinium chloride.

Yellow crystals, slightly soluble in water, practically insoluble in ethanol (96 per cent).

mp: 204 °C to 206 °C.

Berberine chloride used in liquid chromatography complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Goldenseal rhizome (1831)*.

Content: minimum 95 per cent, calculated by the normalisation procedure.

Bergapten. $C_{12}H_8O_4$. (M_r 216.2). *1103700.* [484-20-8]. 5-Methoxypsoralen.

Colourless crystals, practically insoluble in water, sparingly soluble in ethanol (96 per cent) and slightly soluble in glacial acetic acid.

mp: about 188 °C.

Betulin. $C_{30}H_{50}O_2$. (M_r 442.7). *1011100.* [473-98-3].
Lup-20(39)-ene-3β,28-diol.
White or almost white, crystalline powder.
mp: 248 °C to 251 °C.

Bibenzyl. $C_{14}H_{14}$. (M_r 182.3). *1011200.* [103-29-7].
1,2-Diphenylethane.
White or almost white, crystalline powder, practically insoluble in water, very soluble in methylene chloride, freely soluble in acetone, soluble in ethanol (96 per cent).
mp: 50 °C to 53 °C.

Biphenyl. $C_{12}H_{10}$. (M_r 154.2). *1168600.* [92-52-4].
mp: 68 °C to 70 °C.

Biphenyl-4-ol. $C_{12}H_{10}O$. (M_r 170.2). *1011300.* [90-43-7].
4-Phenylphenol.
White or almost white, crystalline powder, practically insoluble in water.
mp: 164 °C to 167 °C.

(–)-α-Bisabolol. $C_{15}H_{26}O$. (M_r 222.4). *1128800.* [23089-26-1].
(2*S*)-6-Methyl-2-[(1*S*)-4-methylcyclohex-3-enyl]hept-5-en-2-ol.
Levomenol.
Colourless, viscous liquid with a slight, characteristic odour, practically insoluble in water, freely soluble in ethanol (96 per cent), in methanol, in toluene, in fatty oils and in essential oils.
d_{20}^{20}: 0.925 to 0.935.
n_D^{20}: 1.492 to 1.500.
$[\alpha]_D^{20}$: –54.5 to –58.0, determined on a 50 g/L solution in *ethanol (96 per cent) R*.
(–)-α-Bisabolol used for gas chromatography complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Matricaria oil (1836)*.
Test solution. A 4 g/L solution in *cyclohexane R*.
Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Bisbenzimide. $C_{25}H_{27}Cl_3N_6O,5H_2O$. ($M_r$ 624). *1103800.* [23491-44-3]. 4-[5-[5-(4-Methylpiperazin-1-yl)benzimidazol-2-yl]benzimidazol-2-yl]phenol trihydrochloride pentahydrate.

Bisbenzimide stock solution. *1103801.*
Dissolve 5 mg of *bisbenzimide R* in *water R* and dilute to 100 mL with the same solvent.
Storage: in the dark.

Bisbenzimide working solution. *1103802.*
Immediately before use, dilute 100 µL of *bisbenzimide stock solution R* to 100 mL with *phosphate-buffered saline pH 7.4 R*.

Bismuth nitrate pentahydrate. $Bi(NO_3)_3,5H_2O$. (M_r 485.1). *1165600.* [10035-06-0].
mp: about 30 °C.

Bismuth subnitrate. $4BiNO_3(OH)_2,BiO(OH)$. (M_r 1462). *1011500.* [1304-85-4].
White or almost white powder, practically insoluble in water.

Bismuth subnitrate R1. *1011501.*
Content: 71.5 per cent to 74.0 per cent of bismuth (Bi), and 14.5 per cent to 16.5 per cent of nitrate, calculated as nitrogen pentoxide (N_2O_5).

Bismuth subnitrate solution. *1011502.*
Dissolve 5 g of *bismuth subnitrate R1* in a mixture of 8.4 mL of *nitric acid R* and 50 mL of *water R* and dilute to 250 mL with *water R*. Filter if necessary.
Acidity. To 10 mL add 0.05 mL of *methyl orange solution R*. 5.0 mL to 6.25 mL of *1 M sodium hydroxide* is required to change the colour of the indicator.

Biuret. $C_2H_5N_3O_2$. (M_r 103.1). *1011600.* [108-19-0].
White or almost white crystals, hygroscopic, soluble in water, sparingly soluble in ethanol (96 per cent).
mp: 188 °C to 190 °C, with decomposition.
Storage: in an airtight container.

Biuret reagent. *1011601.*
Dissolve 1.5 g of *copper sulfate R* and 6.0 g of *sodium potassium tartrate R* in 500 mL of *water R*. Add 300 mL of a carbonate-free 100 g/L solution of *sodium hydroxide R*, dilute to 1000 mL with the same solution and mix.

Blocking solution. *1122400.*
A 10 per cent *V/V* solution of *acetic acid R*.

Blue dextran 2000. *1011700.* [9049-32-5].
Prepared from dextran having an average relative molecular mass of 2×10^6 by introduction of a polycyclic chromophore that colours the substance blue. The degree of substitution is 0.017.
It is freeze-dried and dissolves rapidly and completely in water and aqueous saline solutions.
Absorbance (*2.2.25*). A 1 g/L solution in a *phosphate buffer solution pH 7.0 R* shows an absorption maximum at 280 nm.

Boldine. $C_{19}H_{21}NO_4$. (M_r 327.3). *1118800.* [476-70-0].
1,10-Dimethoxy-6aα-aporphine-2,9-diol.
White or almost white crystalline powder, very slightly soluble in water, soluble in ethanol (96 per cent) and in dilute solutions of acids.
$[\alpha]_D^{25}$: about + 127, determined on a 1 g/L solution in *anhydrous ethanol R*.
mp: about 163 °C.

Boric acid. *1011800.* [10043-35-3].
See *Boric acid (0001)*.

Boric acid solution, saturated, cold. *1011801.*
To 3 g of *boric acid R* add 50 mL of *water R* and shake for 10 min. Place the solution for 2 h in the refrigerator.

Borneol. $C_{10}H_{18}O$. (M_r 154.3). *1011900.* [507-70-0].
endo-1,7,7-Trimethylbicyclo[2.2.1]heptan-2-ol.
Colourless crystals, readily sublimes, practically insoluble in water, freely soluble in ethanol (96 per cent) and in light petroleum.
mp: about 208 °C.
Chromatography. Thin-layer chromatography (*2.2.27*), using *silica gel G R* as the coating substance. Apply to the plate 10 µL of a 1 g/L solution in *toluene R*. Develop over a path of 10 cm using *chloroform R*. Allow the plate to dry in air, spray with *anisaldehyde solution R*, using 10 mL for a plate 200 mm square, and heat at 100-105 °C for 10 min. The chromatogram obtained shows only one principal spot.

Bornyl acetate. $C_{12}H_{20}O_2$. (M_r 196.3). *1012000.* [5655-61-8].
endo-1,7,7-Trimethylbicyclo[2.2.1]hept-2-yl acetate.
Colourless crystals or a colourless liquid, very slightly soluble in water, soluble in ethanol (96 per cent).
mp: about 28 °C.
Chromatography. Thin-layer chromatography (*2.2.27*), using *silica gel G R* as the coating substance. Apply to the plate 10 µL of a 2 g/L solution in *toluene R*. Develop over a path of 10 cm using *chloroform R*. Allow the plate to dry in air, spray with *anisaldehyde solution R*, using 10 mL for a plate 200 mm square, and heat at 100-105 °C for 10 min. The chromatogram obtained shows only one principal spot.

Boron trichloride. BCl_3. (M_r 117.2). *1112000.* [10294-34-5].
Colourless gas. Reacts violently with water. Available as solutions in suitable solvents (2-chloroethanol, methylene chloride, hexane, heptane, methanol).

n_D^{20}: about 1.420.

bp: about 12.6 °C.

Caution: toxic and corrosive.

Boron trichloride-methanol solution. *1112001.*

A 120 g/L solution of BCl_3 in *methanol R*.

Storage: protected from light at – 20 °C, preferably in sealed tubes.

Boron trifluoride. BF_3. (M_r 67.8). *1012100.* [7637-07-2].

Colourless gas.

Boron trifluoride-methanol solution. *1012101.*

A 140 g/L solution of *boron trifluoride R* in *methanol R*.

Brilliant blue. *1012200.* [6104-59-2].

See *acid blue 83 R*.

Bromelains. *1012300.* [37189-34-7].

Concentrate of proteolytic enzymes derived from *Ananas comosus* Merr.

Dull-yellow powder.

Activity. 1 g liberates about 1.2 g of amino-nitrogen from a solution of *gelatin R* in 20 min at 45 °C and pH 4.5.

Bromelains solution. *1012301.*

A 10 g/L solution of *bromelains R* in a mixture of 1 volume of *phosphate buffer solution pH 5.5 R* and 9 volumes of a 9 g/L solution of *sodium chloride R*.

Bromine. Br_2. (M_r 159.8). *1012400.* [7726-95-6].

Brownish-red fuming liquid, slightly soluble in water, soluble in ethanol (96 per cent).

d_{20}^{20}: about 3.1.

Bromine solution. *1012401.*

Dissolve 30 g of *bromine R* and 30 g of *potassium bromide R* in *water R* and dilute to 100 mL with the same solvent.

Bromine water. *1012402.*

Shake 3 mL of *bromine R* with 100 mL of *water R* to saturation.

Storage: over an excess of *bromine R*, protected from light.

Bromine water R1. *1012403.*

Shake 0.5 mL of *bromine R* with 100 mL of *water R*.

Storage: protected from light; use within 1 week.

Bromocresol green. $C_{21}H_{14}Br_4O_5S$. (M_r 698). *1012600.* [76-60-8]. 3′,3″,5′,5″-Tetrabromo-*m*-cresol-sulfonphthalein. 4,4′-(3*H*-2,1-Benzoxathiol-3-ylidene)bis(2,6-dibromo-3-methylphenol)-*S*,*S*-dioxide.

Brownish-white powder, slightly soluble in water, soluble in ethanol (96 per cent) and in dilute solutions of alkali hydroxides.

Bromocresol green-methyl red solution. *1012602.*

Dissolve 0.15 g of *bromocresol green R* and 0.1 g of *methyl red R* in 180 mL of *anhydrous ethanol R* and dilute to 200 mL with *water R*.

Bromocresol green solution. *1012601.*

Dissolve 50 mg of *bromocresol green R* in 0.72 mL of *0.1 M sodium hydroxide* and 20 mL of *ethanol (96 per cent) R* and dilute to 100 mL with *water R*.

Test for sensitivity. To 0.2 mL of the bromocresol green solution add 100 mL of *carbon dioxide-free water R*. The solution is blue. Not more than 0.2 mL of *0.02 M hydrochloric acid* is required to change the colour to yellow.

Colour change: pH 3.6 (yellow) to pH 5.2 (blue).

Bromocresol purple. $C_{21}H_{16}Br_2O_5S$. (M_r 540.2). *1012700.* [115-40-2]. 3′,3″-Dibromo-*o*-cresolsulfonphthalein. 4,4′-(3*H*-2,1-Benzoxathiol-3-ylidene)bis(2-bromo-6-methylphenol)-*S*,*S*-dioxide.

Pinkish powder, practically insoluble in water, soluble in ethanol (96 per cent) and in dilute solutions of alkali hydroxides.

Bromocresol purple solution. *1012701.*

Dissolve 50 mg of *bromocresol purple R* in 0.92 mL of *0.1 M sodium hydroxide* and 20 mL of *ethanol (96 per cent) R* and dilute to 100 mL with *water R*.

Test for sensitivity. To 0.2 mL of the bromocresol purple solution add 100 mL of *carbon dioxide-free water R* and 0.05 mL of *0.02 M sodium hydroxide*. The solution is bluish-violet. Not more than 0.2 mL of *0.02 M hydrochloric acid* is required to change the colour to yellow.

Colour change: pH 5.2 (yellow) to pH 6.8 (bluish-violet).

5-Bromo-2′-deoxyuridine. $C_9H_{11}BrN_2O_5$. (M_r 307.1). *1012500.* [59-14-3]. 5-Bromo-1-(2-deoxy-β-d-*erythro*-pentofuranosyl)-1*H*, 3*H*-pyrimidine-2,4-dione.

mp: about 194 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Idoxuridine (0669)*: apply 5 µL of a 0.25 g/L solution; the chromatogram shows only one principal spot.

Bromomethoxynaphthalene. $C_{11}H_9BrO$. (M_r 237.1). *1159100.* [5111-65-9]. 2-Bromo-6-methoxynaphthalene.

mp: about 109 °C.

Bromophenol blue. $C_{19}H_{10}Br_4O_5S$. (M_r 670). *1012800.* [115-39-9]. 3′,3″,5′,5″-Tetrabromophenolsulfonphthalein. 4,4′-(3*H*-2,1-Benzoxathiol-3-ylidene)bis(2,6-dibromophenol) *S*,*S*-dioxide.

Light orange-yellow powder, very slightly soluble in water, slightly soluble in ethanol (96 per cent), freely soluble in solutions of alkali hydroxides.

Bromophenol blue solution. *1012801.*

Dissolve 0.1 g of *bromophenol blue R* in 1.5 mL of *0.1 M sodium hydroxide* and 20 mL of *ethanol (96 per cent) R* and dilute to 100 mL with *water R*.

Test for sensitivity. To 0.05 mL of the bromophenol blue solution add 20 mL of *carbon dioxide-free water R* and 0.05 mL of *0.1 M hydrochloric acid*. The solution is yellow. Not more than 0.1 mL of *0.1 M sodium hydroxide* is required to change the colour to bluish-violet.

Colour change: pH 2.8 (yellow) to pH 4.4 (bluish-violet).

Bromophenol blue solution R1. *1012802.*

Dissolve 50 mg of *bromophenol blue R* with gentle heating in 3.73 mL of *0.02 M sodium hydroxide* and dilute to 100 mL with *water R*.

Bromophenol blue solution R2. *1012803.*

Dissolve with heating 0.2 g of *bromophenol blue R* in 3 mL of *0.1 M sodium hydroxide* and 10 mL of *ethanol (96 per cent) R*. After solution is effected, allow to cool and dilute to 100 mL with *ethanol (96 per cent) R*.

Bromophos. $C_8H_8BrCl_2O_3PS$. (M_r 366.0). *1123700.* [2104-96-3].

A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

Bromophos-ethyl. $C_{10}H_{12}BrCl_2O_3PS$. (M_r 394.0). *1123800.* [4824-78-6].

A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

Bromothymol blue. $C_{27}H_{28}Br_2O_5S$. (M_r 624). *1012900.* [76-59-5]. 3′,3″-Dibromothymolsulfonphthalein. 4,4′-(3*H*-2,1-Benzoxathiol-3-ylidene)bis(2-bromo-6-isopropyl-3-methylphenol) *S,S*-dioxide.

Reddish-pink or brownish powder, practically insoluble in water, soluble in ethanol (96 per cent) and in dilute solutions of alkali hydroxides.

Bromothymol blue solution R1. *1012901.*

Dissolve 50 mg of *bromothymol blue R* in a mixture of 4 mL of *0.02 M sodium hydroxide* and 20 mL of *ethanol (96 per cent) R* and dilute to 100 mL with *water R*.

Test for sensitivity. To 0.3 mL of *bromothymol blue solution R1* add 100 mL of *carbon dioxide-free water R*. The solution is yellow. Not more than 0.1 mL of *0.02 M sodium hydroxide* is required to change the colour to blue.

Colour change: pH 5.8 (yellow) to pH 7.4 (blue).

Bromothymol blue solution R2. *1012902.*

A 10 g/L solution in *dimethylformamide R*.

Bromothymol blue solution R3. *1012903.*

Warm 0.1 g of *bromothymol blue R* with 3.2 mL of *0.05 M sodium hydroxide* and 5 mL of *ethanol (90 per cent V/V) R*. After solution is effected, dilute to 250 mL with *ethanol (90 per cent V/V) R*.

Bromothymol blue solution R4. *1012904.*

Dissolve 100 mg of *bromothymol blue R* in a mixture of equal volumes of *ethanol 96 per cent R* and *water R* and dilute to 100 mL with the same mixture of solvents. Filter if necessary.

BRP indicator solution. *1013000.*

Dissolve 0.1 g of *bromothymol blue R*, 20 mg of *methyl red R* and 0.2 g of *phenolphthalein R* in *ethanol (96 per cent) R* and dilute to 100 mL with the same solvent. Filter.

Brucine. $C_{23}H_{26}N_2O_4,2H_2O$. (M_r 430.5). *1013100.* [357-57-3]. 10,11-Dimethoxystrychnine.

Colourless crystals, slightly soluble in water, freely soluble in ethanol (96 per cent).

mp: about 178 °C.

Butanal. C_4H_8O. (M_r 72.1). *1134400.* [123-72-8]. Butyraldehyde.

d_{20}^{20}: 0.806.

n_D^{20}: 1.380.

bp: 75 °C.

Butane-1,4-diol. $HO(CH_2)_4OH$. (M_r 90.12). *1174800.* [110-63-4].

Butanol. $C_4H_{10}O$. (M_r 74.1). *1013200.* [71-36-3]. *n*-Butanol. 1-Butanol.

Clear, colourless liquid, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.81.

bp: 116 °C to 119 °C.

2-Butanol R1. $C_4H_{10}O$. (M_r 74.1). *1013301.* [78-92-2]. *sec*-Butyl alcohol.

Content: minimum 99.0 per cent.

Clear, colourless liquid, soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.81.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 99 °C and 100 °C.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Isopropyl alcohol (0970)*.

Butyl acetate. $C_6H_{12}O_2$. (M_r 116.2). *1013400.* [123-86-4].

Clear, colourless liquid, flammable, slightly soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.88.

n_D^{20}: about 1.395.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 123 °C and 126 °C.

Butyl acetate R1. *1013401.*

Content: minimum 99.5 per cent, determined by gas chromatography.

Clear, colourless liquid, flammable, slightly soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.883.

n_D^{20}: about 1.395.

Butanol: maximum 0.2 per cent, determined by gas chromatography.

n-Butyl formate: maximum 0.1 per cent, determined by gas chromatography.

n-Butyl propionate: maximum 0.1 per cent, determined by gas chromatography.

Water: maximum 0.1 per cent.

Butylamine. $C_4H_{11}N$. (M_r 73.1). *1013600.* [109-73-9]. 1-Butanamine.

Distil and use within one month.

Colourless liquid, miscible with water, with ethanol (96 per cent).

n_D^{20}: about 1.401.

bp: about 78 °C.

***tert*-Butylamine.** *1100900.* [75-64-9].

See *1,1-dimethylethylamine R*.

Butylated hydroxytoluene. *1013800.* [128-37-0].

See *Butylhydroxytoluene R*.

Butylboronic acid. $C_4H_{11}BO_2$. (M_r 101.9). *1013700.* [4426-47-5].

Content: minimum 98 per cent.

mp: 90 °C to 92 °C.

***tert*-Butylhydroperoxide.** $C_4H_{10}O_2$. (M_r 90.1). *1118000.* [75-91-2]. 1,1-Dimethylethylhydroperoxide.

Flammable liquid, soluble in organic solvents.

d_{20}^{20}: 0.898.

n_D^{20}: 1.401.

bp: 35 °C.

Butyl 4-hydroxybenzoate. *1103900.* [94-26-8].

See *Butyl parahydroxybenzoate R*.

Butylhydroxytoluene. *1013800.* [128-37-0].

See *Butylhydroxytoluene (0581)*.

Butyl methacrylate. $C_8H_{14}O_2$. (M_r 142.2). *1145400.* [97-88-1]. Butyl 2-methylpropenoate.

Clear, colourless solution.

d_4^{20}: about 0.894.

n_D^{20}: about 1.424.

bp: about 163 °C.

***tert*-Butyl methyl ether.** *1013900.* [1634-04-4].

See *1,1-dimethylethyl methyl ether R*.

Butyl parahydroxybenzoate. *1103900.* [94-26-8].

See *Butyl parahydroxybenzoate (0881)*.

Butyric acid. $C_4H_8O_2$. (M_r 88.1). *1014000.* [107-92-6]. Butanoic acid.

Content: minimum 99.0 per cent.

Oily liquid, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: about 0.96.

n_D^{20}: about 1.398.

bp: about 163 °C.

Butyrolactone. $C_4H_6O_2$. (M_r 86.1). *1104000.* [96-48-0]. Dihydro-2(3*H*)-furanone. γ-Butyrolactone.

Oily liquid, miscible with water, soluble in methanol.

n_D^{25}: about 1.435.

bp: about 204 °C.

Cadmium. Cd. (A_r 112.4). *1014100.* [7440-43-9].

Silvery-white, lustrous metal, practically insoluble in water, freely soluble in nitric acid and in hot hydrochloric acid.

Cadmium nitrate tetrahydrate. $Cd(NO_3)_2,4H_2O$. (M_r 308.5). *1174900.* [10022-68-1].

Hygroscopic orthorhombic crystals, very soluble in water, soluble in acetone and in ethanol (96 per cent).

mp: about 59.5 °C.

Caesium chloride. CsCl. (M_r 168.4). *1014200.* [7647-17-8].

White or almost white powder, very soluble in water, freely soluble in methanol, practically insoluble in acetone.

Caffeic acid. $C_9H_8O_4$. (M_r 180.2). *1014300.* [331-39-5]. (*E*)-3-(3,4-Dihydroxyphenyl)propenoic acid.

White or almost white crystals or plates, freely soluble in hot water and in ethanol (96 per cent), sparingly soluble in cold water.

mp: about 225 °C, with decomposition.

Absorbance (*2.2.25*). A freshly prepared solution at pH 7.6 shows 2 absorption maxima at 293 nm and 329 nm.

Caffeine. *1014400.* [58-08-2].

See *Caffeine (0267).*

Calcium carbonate. *1014500.* [471-34-1].

See *Calcium carbonate (0014).*

Calcium carbonate R1. *1014501.*

Complies with the requirements prescribed for *calcium carbonate R* with the following additional requirement.

Chlorides (*2.4.4*): maximum 50 ppm.

Calcium chloride. *1014600.* [10035-04-8].

See *Calcium chloride (0015).*

Calcium chloride solution. *1014601.*

A 73.5 g/L solution.

Calcium chloride solution, 0.01 M. *1014602.*

Dissolve 0.147 g of *calcium chloride R* in *water R* and dilute to 100.0 mL with the same solvent.

Calcium chloride solution, 0.02 M. *1014603.*

Dissolve 2.94 g of *calcium chloride R* in 900 mL of *water R*, adjust to pH 6.0 to 6.2 and dilute to 1000.0 mL with *water R*.

Storage: at 2 °C to 8 °C.

Calcium chloride solution, 0.025 M. *1014604.*

Dissolve 0.368 g of *calcium chloride R* in *water R* and dilute to 100.0 mL with the same solvent.

Calcium chloride R1. $CaCl_2,4H_2O$. (M_r 183.1). *1014700.* Calcium chloride tetrahydrate.

Iron: maximum 0.05 ppm.

Calcium chloride, anhydrous. $CaCl_2$. (M_r 111.0). *1014800.* [10043-52-4].

Content: minimum 98.0 per cent (dried substance).

White or almost white granules, deliquescent, very soluble in water, freely soluble in ethanol (96 per cent) and in methanol.

Loss on drying (*2.2.32*): maximum 5.0 per cent, determined by drying in an oven at 200 °C.

Storage: in an airtight container, protected from moisture.

Calcium hydroxide. $Ca(OH)_2$. (M_r 74.1). *1015000.* [1305-62-0]. Calcium dihydroxide.

White or almost white powder, almost completely soluble in 600 parts of water.

Calcium hydroxide solution. *1015001.*

A freshly prepared saturated solution.

Calcium lactate. *1015100.* [41372-22-9].

See *Calcium lactate pentahydrate (0468).*

Calcium phosphate monobasic monohydrate. $CaH_4O_8P_2,H_2O$. (M_r 252.1). *1157200.* [10031-30-8]. Calcium tetrahydrogen bisphosphate monohydrate. Phosphoric acid calcium salt (2:1) monohydrate.

White or almost white, crystalline powder, soluble in water.

Calcium sulfate. $CaSO_4,{}^1/_2H_2O$. (M_r 145.1). *1015200.* [10034-76-1]. Calcium sulfate hemihydrate.

White or almost white powder, soluble in about 1500 parts of water, practically insoluble in ethanol (96 per cent). When mixed with half its mass of water it rapidly solidifies to a hard and porous mass.

Calcium sulfate solution. *1015201.*

Shake 5 g of *calcium sulfate R* with 100 mL of *water R* for 1 h and filter.

Calconecarboxylic acid. $C_{21}H_{14}N_2O_7S,3H_2O$. ($M_r$ 492.5). *1015300.* [3737-95-9]. 2-Hydroxy-1-(2-hydroxy-4-sulfo-1-naphthylazo)naphthalene-3-carboxylic acid.

Brownish-black powder, slightly soluble in water, very slightly soluble in acetone and in ethanol (96 per cent), sparingly soluble in dilute solutions of sodium hydroxide.

Calconecarboxylic acid triturate. *1015301.*

Mix 1 part of *calconecarboxylic acid R* with 99 parts of *sodium chloride R*.

Test for sensitivity. Dissolve 50 mg of calconecarboxylic acid triturate in a mixture of 2 mL of *strong sodium hydroxide solution R* and 100 mL of *water R*. The solution is blue but becomes violet on addition of 1 mL of a 10 g/L solution of *magnesium sulfate R* and 0.1 mL of a 1.5 g/L solution of *calcium chloride R* and turns pure blue on addition of 0.15 mL of *0.01 M sodium edetate*.

Camphene. $C_{10}H_{16}$. (M_r 136.2). *1139200.* [79-92-5]. 2,2-Dimethyl-3-methylenebicyclo[2.2.1]heptane.

Camphene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Rosemary Oil (1846).*

Content: minimum 90 per cent, calculated by the normalisation procedure.

Camphor. *1113000.* [76-22-2].

See *Camphor, racemic (0655).*

Camphor used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Lavender oil (1338).*

Test solution. A 10 g/L solution of the substance to be examined in *hexane R*.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

(1*S*)-(+)-10-Camphorsulfonic acid. $C_{10}H_{16}O_4S$. (M_r 232.3). *1104100.* [3144-16-9]. (1*S*,4*R*)-(+)-2-Oxo-10-bornenesulfonic acid. [(1*S*)-7,7-Dimethyl-2-oxobicyclo[2.2.1]heptan-1-yl]methanesulfonic acid. Reychler's acid.

Prismatic crystals, hygroscopic, soluble in water.

Content: minimum 99.0 per cent of (1*S*)-(+)-10-camphorsulfonic acid.

$[\alpha]_D^{20}$: + 20 ± 1, determined on a 43 g/L solution.

mp: about 194 °C, with decomposition.

ΔA (*2.2.41*): 10.2×10^3 determined at 290.5 nm on a 1.0 g/L solution.

Capric acid. $C_{10}H_{20}O_2$. (M_r 172.3). *1142000.* [334-48-5]. Decanoic acid.

Crystalline solid, very slightly soluble in water, soluble in anhydrous ethanol.

bp: about 270 °C.

mp: about 31.4 °C.

Capric acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

Capric alcohol. *1024700.*

See *Decanol R.*

Caproic acid. $C_6H_{12}O_2$. (M_r 116.2). *1142100.* [142-62-1]. Hexanoic acid.

Oily liquid, sparingly soluble in water.

d_4^{20}: about 0.926.

n_D^{20}: about 1.417.

bp: about 205 °C.

Caproic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

ε-Caprolactam. $C_6H_{11}NO$. (M_r 113.2). *1104200.* [105-60-2]. Hexane-6-lactam.

Hygroscopic flakes, freely soluble in water, in anhydrous ethanol and in methanol.

mp: about 70 °C.

Caprylic acid. $C_8H_{16}O_2$. (M_r 144.2). *1142200.* [124-07-2]. Octanoic acid.

Slightly yellow, oily liquid.

d_4^{20}: about 0.910.

n_D^{20}: about 1.428.

bp: about 239.7 °C.

mp: about 16.7 °C.

Caprylic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

Capsaicin. $C_{18}H_{27}NO_3$. (M_r 305.4). *1147900.* [404-86-4]. (*E*)-*N*-[(4-Hydroxy-3-methoxyphenyl)methyl]-8-methylnon-6-enamide.

White or almost white, crystalline powder, practically insoluble in water, freely soluble in anhydrous ethanol.

mp: about 65 °C.

Capsaicin used in the assay in Capsicum (1859) complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Capsicum (1859).*

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Carbazole. $C_{12}H_9N$. (M_r 167.2). *1015400.* [86-74-8]. Dibenzopyrrole.

Crystals, practically insoluble in water, freely soluble in acetone, slightly soluble in anhydrous ethanol.

mp: about 245 °C.

Carbomer. *1015500.* [9007-20-9].

A cross-linked polymer of acrylic acid; it contains a large proportion (56 per cent to 68 per cent) of carboxylic acid (CO_2H) groups after drying at 80 °C for 1 h. Average relative molecular mass about 3×10^6.

pH (*2.2.3*): about 3 for a 10 g/L suspension.

Carbon dioxide. *1015600.* [124-38-9].

See *Carbon dioxide (0375).*

Carbon dioxide R1. CO_2. (M_r 44.01). *1015700.* [124-38-9].

Content: minimum 99.995 per cent *V/V.*

Carbon monoxide: less than 5 ppm.

Oxygen: less than 25 ppm.

Nitric oxide: less than 1 ppm.

Carbon dioxide R2. CO_2. (M_r 44.01). *1134500.* [124-38-9].

Content: minimum 99 per cent *V/V.*

Carbon disulfide. CS_2. (M_r 76.1). *1015800.* [75-15-0].

Colourless or yellowish, flammable liquid, practically insoluble in water, miscible with anhydrous ethanol.

d_{20}^{20}: about 1.26.

bp: 46 °C to 47 °C.

Carbon for chromatography, graphitised. *1015900.*

Carbon chains having a length greater than C_9.

Particle size: 400 µm to 850 µm.

Relative density: 0.72.

Surface area: 10 m^2/g.

Do not use at a temperature higher than 400 °C.

Carbon for chromatography, graphitised R1. *1153500.*

Porous spherical carbon particles comprised of flat sheets of hexagonally arranged carbon atoms.

Particle size: 5 µm to 7 µm.

Pore volume: 0.7 cm^3/g.

Carbon monoxide. CO. (M_r 28.01). *1016000.* [630-08-0].

Content: minimum 99.97 per cent *V/V.*

Carbon monoxide R1. CO. (M_r 28.01). *1134600.* [630-08-0].

Content: minimum 99 per cent *V/V.*

Carbon tetrachloride. CCl_4. (M_r 153.8). *1016100.* [56-23-5]. Tetrachloromethane.

Clear, colourless liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: 1.595 to 1.598.

bp: 76 °C to 77 °C.

Carbophenothion. $C_{11}H_{16}ClO_2PS_3$. (M_r 342.9). *1016200.* [786-19-6]. *O,O*-Diethyl *S*-[[(4-chlorophenyl)thio]methyl]-phosphorodithioate.

Yellowish liquid, practically insoluble in water, miscible with organic solvents.

d_4^{25}: about 1.27.

For the monograph *Wool Fat (0134),* a suitable certified reference solution (10 ng/µl in iso-octane) may be used.

Car-3-ene. $C_{10}H_{16}$. (M_r 136.2). *1124000.* [498-15-7]. 3,7,7-Trimethylbicyclo[4.1.0]hept-3-ene. 4,7,7-Trimethyl-3-norcarene.

Liquid with a pungent odour, slightly soluble in water, soluble in organic solvents.

d_{20}^{20}: about 0.864.

n_D^{20}: 1.473 to 1.474.

$[\alpha]_D^{20}$: + 15 to + 17.

bp: 170 °C to 172 °C.

Car-3-ene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Nutmeg oil (1552).*

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Carminic acid. $C_{22}H_{20}O_{13}$. (M_r 492.4). *1156700.* [1260-17-9]. 7-α-D-Glucopyranosyl-3,5,6,8-tetrahydroxy-1-methyl-9,10-dioxo-9,10-dihydroanthracene-2-carboxylic acid.

Dark red powder, very slightly soluble in water, soluble in dimethyl sulfoxide, very slightly soluble in ethanol (96 per cent).

Carob bean gum. *1104500.*

The ground endosperm of the fruit kernels of *Ceratonia siliqua* L. Taub.

White or almost white powder containing 70 per cent to 80 per cent of a water-soluble gum consisting mainly of galactomannoglycone.

Carvacrol. $C_{10}H_{14}O$. (M_r 150.2). *1016400.* [499-75-2]. 5-Isopropyl-2-methylphenol.

Brownish liquid, practically insoluble in water, very soluble in ethanol (96 per cent).

d_{20}^{20}: about 0.975.

n_D^{20}: about 1.523.

bp: about 237 °C.

Carvacrol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*

Test solution. Dissolve 0.1 g in about 10 mL of *acetone R.*

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Carveol. $C_{10}H_{16}O$. (M_r 152.2). *1160400.* [99-48-9]. *p*-Mentha-1(6),8-dien-2-ol. 2-Methyl-5-(1-methylethenyl)cyclohex-2-enol.

The substance contains a variable content of *trans*- and *cis*-carveol.

Carveol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the test for chromatographic profile in the monograph *Caraway oil (1817).*

Content: minimum 97 per cent, calculated by the normalisation procedure.

Carvone. $C_{10}H_{14}O$. (M_r 150.2). *1016500.* [2244-16-8]. (+)-*p*-Mentha-6,8-dien-2-one. (5*S*)-2-Methyl-5-(1-methylethenyl)-cyclohex-2-enone.

Liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.965

n_D^{20}: about 1.500.

$[\alpha]_D^{20}$: about + 61.

bp: about 230 °C.

Carvone used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405)* using the substance to be examined as the test solution.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Carvone R1. *1016501.*

Complies with the requirements prescribed for *carvone R* with the following additional requirement.

Assay. Gas chromatography (*2.2.28*) as prescribed in the test for chiral purity in the monograph *Caraway oil (1817).*

Content: minimum 98 per cent.

(–)-Carvone. $C_{10}H_{14}O$. (M_r 150.2). *1160500.* [6485-40-1]. (−)-*p*-Mentha-1(6),8-dien-2-one. (5*R*)-2-Methyl-5-(1-methylethenyl)cyclohex-2-enone.

Liquid.

d_{20}^{20}: about 0.965.

n_D^{20}: about 1.4988.

$[\alpha]_D^{20}$: about – 62.

bp: about 230 °C.

Assay. Gas chromatography (*2.2.28*) as prescribed in the test for chiral purity in the monograph *Caraway oil (1817).*

Content: minimum 99 per cent.

β-Caryophyllene. $C_{15}H_{24}$. (M_r 204.4). *1101000.* [87-44-5]. (*E*)-(1*R*,9*S*)-4,11,11-Trimethyl-8-methylenebicyclo[7.2.0]undec-4-ene.

Oily liquid, practically insoluble in water, miscible with ethanol (96 per cent).

β-Caryophyllene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Clove oil (1091).*

Test solution. The substance to be examined.

Content: minimum 90.0 per cent, calculated by the normalisation procedure.

Caryophyllene oxide. $C_{15}H_{24}O$. (M_r 220.4). *1149000.* [1139-30-6]. (-)-β-Caryophyllene epoxide. (1*R*,4*R*,6*R*,10*S*)-4,12,12-Trimethyl-9-methylene-5-oxatricyclo[8.2.0.0^{4,6}]dodecane.

Colourless, fine crystals with lumps.

mp: 62 °C to 63 °C.

Caryophyllene oxide used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Turpentine oil, Pinus pinaster type (1627).*

Content: minimum 99.0 per cent, calculated by the normalisation procedure.

Casein. *1016600.* [9000-71-9].

Mixture of related phosphoproteins obtained from milk.

White or almost white, amorphous powder or granules, very slightly soluble in water and in non-polar organic solvents. It dissolves in concentrated hydrochloric acid giving a pale-violet solution. It forms salts with acids and bases. Its isoelectric point is at about pH 4.7. Alkaline solutions are laevorotatory.

Casticin. $C_{19}H_{18}O_8$. (M_r 374.3). *1162200.* [479-91-4]. 5-Hydroxy-2-(3-hydroxy-4-methoxyphenyl)-3,6,7-trimethoxy-4*H*-1-benzopyran-4-one.

Yellow crystals.

Catalpol. $C_{15}H_{22}O_{10}$. (M_r 362.3). *1142300.* [2415-24-9]. (1a*S*,1b*S*,2*S*,5a*R*,6*S*,6a*S*)-6-Hydroxy-1a-(hydroxymethyl)-1a,1b,2,5a,6,6a-hexahydrooxireno[4,5]cyclopenta[1,2-*c*]pyran-2-yl β-D-glucopyranoside.

mp: 203 °C to 205 °C.

Catechin. $C_{15}H_{14}O_6,xH_2O$. (M_r 290.3 for the anhydrous substance). *1119000.* [154-23-4]. (+)-(2*R*,3*S*)-2-(3,4-Dihydroxyphenyl)-3,4-dihydro-2*H*-chromene-3,5,7-triol. Catechol. Cianidanol. Cyanidol.

Cation exchange resin. *1016700.*

A resin in protonated form with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with 8 per cent of divinylbenzene. It is available as beads and the particle size is specified after the name of the reagent in the tests where it is used.

Cation exchange resin R1. *1121900.*

A resin in protonated form with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with 4 per cent of divinylbenzene. It is available as beads and the particle size is specified after the name of the reagent in the tests where it is used.

Cation-exchange resin, strong. *1156800.*

Strong cation-exchange resin in protonated form with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with divinylbenzene. The particle size is specified after the name of the reagent in the tests where it is used.

Cation exchange resin (calcium form), strong. *1104600.*

Resin in calcium form with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with 8 per cent of divinylbenzene. The particle size is specified after the name of the reagent in the tests where it is used.

Cation-exchange resin (sodium form), strong. *1176100.*

Resin in sodium form with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with divinylbenzene. The particle size is specified after the name of the reagent in the tests where it is used.

Cellulose for chromatography. *1016800.* [9004-34-6].

Fine, white or almost white, homogeneous powder with an average particle size less than 30 µm.

Preparation of a thin layer. Suspend 15 g in 100 mL of *water R* and homogenise in an electric mixer for 60 s. Coat carefully cleaned plates with a layer 0.1 mm thick using a spreading device. Allow to dry in air.

Cellulose for chromatography R1. *1016900.*

Microcrystalline cellulose. A fine, white or almost white homogeneous powder with an average particle size less than 30 µm.

Preparation of a thin layer. Suspend 25 g in 90 mL of *water R* and homogenise in an electric mixer for 60 s. Coat carefully cleaned plates with a layer 0.1 mm thick using a spreading device. Allow to dry in air.

Cellulose for chromatography F_{254}. *1017000.*

Microcrystalline cellulose F_{254}. A fine, white or almost white, homogeneous powder with an average particle size less than 30 µm, containing a fluorescent indicator having an optimal intensity at 254 nm.

Preparation of a thin layer. Suspend 25 g in 100 mL of *water R* and homogenise using an electric mixer for 60 s. Coat carefully cleaned plates with a layer 0.1 mm thick using a spreading device. Allow to dry in air.

Cerium sulfate. $Ce(SO_4)_2,4H_2O$. (M_r 404.3). *1017300.* [123333-60-8]. Cerium(IV) sulfate. Ceric sulfate.

Yellow or orange-yellow, crystalline powder or crystals, very slightly soluble in water, slowly soluble in dilute acids.

Cerous nitrate. $Ce(NO_3)_3,6H_2O$. (M_r 434.3). *1017400.* [10294-41-4]. Cerium trinitrate hexahydrate.

Colourless or pale yellow, crystalline powder, freely soluble in water and in ethanol (96 per cent).

Cetostearyl alcohol. *1017500.* [67762-27-0].

See *Cetostearyl alcohol (0702).*

Cetrimide. *1017600.* [8044-71-1].

See *Cetrimide (0378).*

Cetyl alcohol. $C_{16}H_{34}O$. (M_r 242.4). *1160600.* [36653-82-4]. Hexadecan-1-ol.

Content: minimum 95.0 per cent.

mp: about 48 °C.

Cetylpyridinium chloride monohydrate. $C_{21}H_{38}ClN,H_2O$. (M_r 358.0). *1162800.* [6004-24-6]. 1-Hexadecylpyridinium chloride monohydrate.

White or almost white powder, freely soluble in water and in ethanol (96 per cent).

mp: 80 °C to 83 °C.

Cetyltrimethylammonium bromide. $C_{19}H_{42}BrN$. (M_r 364.5). *1017700.* [57-09-0]. Cetrimonium bromide. *N*-Hexadecyl-*N,N,N*-trimethylammonium bromide.

White or almost white, crystalline powder, soluble in water, freely soluble in ethanol (96 per cent).

mp: about 240 °C.

Chamazulene. $C_{14}H_{16}$. (M_r 184.3). *1148000.* [529-05-5]. 7-Ethyl-1,4-dimethylazulene.

Blue liquid, very slightly soluble in water, soluble in ethanol (96 per cent), miscible with fatty oils, with essential oils and with liquid paraffin, soluble with discolouration in phosphoric acid (85 per cent *m/m*) and sulfuric acid (50 per cent *V/V*).

Appearance of solution. 50 mg is soluble in 2.5 mL of *hexane R*. The blue solution is clear in a thin-layer obtained by tilting the test-tube.

Chamazulene used for gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Matricaria oil (1836).*

Test solution: a 4 g/L solution in *cyclohexane R*.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Charcoal, activated. *1017800.* [64365-11-3].

See *Activated charcoal (0313).*

Chloral hydrate. *1017900.* [302-17-0].

See *Choral hydrate (0265).*

Chloral hydrate solution. *1017901.*

A solution of 80 g in 20 mL of *water R*.

Chloramine. *1018000.* [7080-50-4].

See *Tosylchloramide sodium (0381).*

Chloramine solution. *1018001.*

A 20 g/L solution. Prepare immediately before use.

Chloramine solution R1. *1018002.*

A 0.1 g/L solution of *chloramine R*. Prepare immediately before use.

Chloramine solution R2. *1018003.*

A 0.2 g/L solution. Prepare immediately before use.

Chlordane. $C_{10}H_6Cl_8$. (M_r 409.8). *1124100.* [12789-03-6].

bp: about 175 °C.

mp: about 106 °C.

A suitable certified reference solution of technical grade (10 ng/µl in iso-octane) may be used.

Chlordiazepoxide. *1113200.* [58-25-3].

See *Chlordiazepoxide (0656).*

Chlorfenvinphos. $C_{12}H_{14}Cl_3O_4P$. (M_r 359.6). *1124200.* [470-90-6].

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Chloroacetanilide. C_8H_8ClNO. (M_r 169.6). *1018100.* [539-03-7]. 4′-Chloroacetanilide.

Content: minimum 95 per cent.

Crystalline powder, practically insoluble in water, soluble in ethanol (96 per cent).

mp: about 178 °C.

Chloroacetic acid. $C_2H_3ClO_2$. (M_r 94.5). *1018200.* [79-11-8].
Colourless or white or almost white crystals, deliquescent, very soluble in water, soluble in ethanol (96 per cent).
Storage: in an airtight container.

Chloroaniline. C_6H_6ClN. (M_r 127.6). *1018300.* [106-47-8]. 4-Chloroaniline.
Crystals, soluble in hot water, freely soluble in ethanol (96 per cent).
mp: about 71 °C.

4-Chlorobenzenesulfonamide. $C_6H_6ClNO_2S$. (M_r 191.6). *1097400.* [98-64-6].
White or almost white powder.
mp: about 145 °C.

2-Chlorobenzoic acid. $C_7H_5ClO_2$. (M_r 156.6). *1139300.* [118-91-2].
Soluble in water, slightly soluble in anhydrous ethanol.
bp: about 285 °C.
mp: about 140 °C.

Chlorobutanol. *1018400.* [57-15-8].
See *Anhydrous chlorobutanol (0382)*.

2-Chloro-2-deoxy-D-glucose. $C_6H_{11}ClO_5$. (M_r 198.6). *1134700.* [14685-79-1].
White or almost white crystalline, very hygroscopic powder, soluble in water and in dimethyl sulfoxide, practically insoluble in ethanol (96 per cent).

2-Chloroethanol. C_2H_5ClO. (M_r 80.5). *1097500.* [107-07-3].
Colourless liquid, soluble in ethanol (96 per cent).
d_{20}^{20}: about 1.197.
n_D^{20}: about 1.442.
bp: about 130 °C.
mp: about – 89 °C.

2-Chloroethanol solution. *1097501.*
Dissolve 125 mg of *2-chloroethanol R* in *2-propanol R* and dilute to 50 mL with the same solvent. Dilute 5 mL of the solution to 50 mL with *2-propanol R*.

Chloroethylamine hydrochloride. $C_2H_7Cl_2N$. (M_r 116.0). *1124300.* [870-24-6]. 2-Chloroethanamine hydrochloride.
mp: about 145 °C.

(2-Chloroethyl)diethylamine hydrochloride. $C_6H_{15}Cl_2N$. (M_r 172.1). *1018500.* [869-24-9].
White or almost white, crystalline powder, very soluble in water and in methanol, freely soluble in methylene chloride, practically insoluble in hexane.
mp: about 211 °C.

Chloroform. $CHCl_3$. (M_r 119.4). *1018600.* [67-66-3]. Trichloromethane.
Clear, colourless liquid, slightly soluble in water, miscible with ethanol (96 per cent).
d_{20}^{20}: 1.475 to 1.481.
bp: about 60 °C.
Ethanol: 0.4 per cent *m/m* to 1.0 per cent *m/m*.
Introduce 1.00 g (*m* g) into a ground-glass-stoppered flask. Add 15.0 mL of *nitrochromic reagent R*, close the flask, shake vigorously for 2 min and allow to stand for 15 min. Add 100 mL of *water R* and 5 mL of a 200 g/L solution of *potassium iodide R*. After 2 min titrate with *0.1 M sodium thiosulfate*, using 1 mL of *starch solution R* as indicator, until a light green colour is obtained (n_1 mL of *0.1 M sodium thiosulfate*). Carry out a blank assay (n_2 mL of *0.1 M sodium thiosulfate*). Calculate the percentage of ethanol using the following expression:

$$\frac{(n_2 - n_1)\,0.115}{m}$$

Chloroform, acidified. *1018601.*
To 100 mL of *chloroform R* add 10 mL of *hydrochloric acid R*. Shake, allow to stand and separate the 2 layers.

Chloroform, ethanol-free. *1018602.*
Shake 200 mL of *chloroform R* with four quantities, each of 100 mL, of *water R*. Dry over 20 g of *anhydrous sodium sulfate R* for 24 h. Distil the filtrate over 10 g of *anhydrous sodium sulfate R*. Discard the first 20 mL of distillate. Prepare immediately before use.

Chloroform stabilised with amylene. $CHCl_3$. (M_r 119.4). *1018700.*
Clear, colourless liquid, slightly soluble in water, miscible with ethanol (96 per cent).
Water: maximum 0.05 per cent.
Residue on evaporation: maximum 0.001 per cent.
Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 50 per cent at 255 nm, 80 per cent at 260 nm, 98 per cent at 300 nm.
Content: minimum 99.8 per cent of $CHCl_3$, determined by gas chromatography.

Chlorogenic acid. $C_{16}H_{18}O_9$. (M_r 354.3). *1104700.* [327-97-9]. (1*S*,3*R*,4*R*,5*R*)-3-[(3,4-Dihydroxycinnamoyl)oxy]-1,4,5-trihydroxycyclohexanecarboxylic acid.
White or almost white, crystalline powder or needles, freely soluble in boiling water, in acetone and in ethanol (96 per cent).
$[\alpha]_D^{26}$: about – 35.2.
mp: about 208 °C.
Chromatography. Thin-layer chromatography *(2.2.27)* as prescribed on Identification A in the monograph *Belladonna leaf dry extract, standardised (1294)*; the chromatogram shows only one principal zone.
Chlorogenic acid used in liquid chromatography complies with the following additional test.
Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Artichoke Leaf (1866)*.
Content: minimum 97.0 per cent.

3-Chloro-2-methylaniline. C_7H_8ClN. (M_r 141.6). *1139400.* [87-60-5]. 6-Chloro-2-toluidine.
Not miscible with water, slightly soluble in anhydrous ethanol.
d_{20}^{20}: about 1.171.
n_D^{20}: about 1.587.
bp: about 115 °C.
mp: about 2 °C.

2-Chloro-*N*-(2,6-dimethylphenyl)acetamide. $C_{10}H_{12}ClNO$. (M_r 197.7). *1168700.* [1131-01-7].

2-Chloronicotinic acid. $C_6H_4ClNO_2$. (M_r 157.6). *1157300.* [2942-59-8]. 2-Chloropyridine-3-carboxylic acid.
White or almost white powder.
mp: about 177 °C.
Content: minimum 95 per cent.

2-Chloro-4-nitroaniline. $C_6H_5ClN_2O_2$. (M_r 172.6). *1018800.* [121-87-9].
Yellow, crystalline powder, freely soluble in methanol.
mp: about 107 °C.
Storage: protected from light.

Chlorophenol. C_6H_5ClO. (M_r 128.6). *1018900.* [106-48-9]. 4-Chlorophenol.
Colourless or almost colourless crystals, slightly soluble in water, very soluble in ethanol (96 per cent) and in solutions of alkali hydroxides.
mp: about 42 °C.

Chloroplatinic acid. $H_2Cl_6Pt,6H_2O$. (M_r 517.9). *1019000.* [18497-13-7]. Hydrogen hexachloroplatinate(IV) hexahydrate.
Content: minimum 37.0 per cent *m/m* of platinum (A_r 195.1).
Brownish-red crystals or a crystalline mass, very soluble in water, soluble in ethanol (96 per cent).
Assay. Ignite 0.200 g to constant mass at 900 ± 50 °C and weigh the residue (platinum).
Storage: protected from light.

3-Chloropropane-1,2-diol. $C_3H_7ClO_2$. (M_r 110.5). *1097600.* [96-24-2].
Colourless liquid, soluble in water and ethanol (96 per cent).
d_{20}^{20}: about 1.322.
n_D^{20}: about 1.480.
bp: about 213 °C.

5-Chloroquinolin-8-ol. C_9H_6ClNO. (M_r 179.6). *1156900.* [130-16-5]. 5-Chlorooxine.
Sparingly soluble in cold dilute hydrochloric acid.
mp: about 123 °C.
Content: minimum 95.0 per cent.

4-Chlororesorcinol. $C_6H_5ClO_2$. (M_r 144.6). *1177700.* [95-88-5]. 4-Chlorobenzene-1,3-diol. 1,3-Dihydroxy-4-chlorobenzene.
mp: 106 °C to 108 °C.

5-Chlorosalicylic acid. $C_7H_5ClO_3$. (M_r 172.6). *1019100.* [321-14-2].
White or almost white, crystalline powder, soluble in methanol.
mp: about 173 °C.

Chlorothiazide. *1112100.* [58-94-6].
See *Chlorothiazide (0385).*

Chlorotrimethylsilane. C_3H_9ClSi. (M_r 108.6). *1019300.* [75-77-4].
Clear, colourless liquid, fuming in air.
d_{20}^{20}: about 0.86.
n_D^{20}: about 1.388.
bp: about 57 °C.

Chlorpyriphos. $C_9H_{11}Cl_3NO_3PS$. (M_r 350.6). *1124400.* [2921-88-2].
bp: about 200 °C.
mp: 42 °C to 44 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Chlorpyriphos-methyl. $C_7H_7Cl_3NO_3PS$. (M_r 322.5). *1124500.* [5598-13-0].
mp: 45 °C to 47 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Chlortetracycline hydrochloride. *1145500.*
See *Chlortetracycline hydrochloride (0173).*

(5α)-Cholestane. $C_{27}H_{48}$. (M_r 372.7). *1167900.* [481-21-0].
Slightly soluble in anhydrous ethanol.
mp: about 81 °C.

Cholesterol. *1019400.* [57-88-5].
See *Cholesterol (0993).*

Choline chloride. $C_5H_{14}ClNO$. (M_r 139.6). *1019500.* [67-48-1]. (2-Hydroxyethyl)trimethylammonium chloride.
Deliquescent crystals, very soluble in water and in ethanol (96 per cent).
Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Suxamethonium chloride (0248)*: apply 5 µL of a 0.2 g/L solution in *methanol R*; the chromatogram shows one principal spot.
Storage: in an airtight container.

Chondroitinase ABC. *1162900.*
Pectin lyase-like enzyme secreted by *Flavobacterium heparinum*. Available in vials containing 5-10 units. It cleaves both glucuronate-containing disaccharides, e.g. chondroitin sulfate, and iduronate-containing disaccharides, e.g. dermatan sulfate.

Chondroitinase AC. *1163000.*
Pectin lyase-like enzyme secreted by *Flavobacterium heparinum*. Available in vials containing 5-10 units. It cleaves only glucuronate-containing disaccharides, e.g. chondroitin sulfate.

Chromazurol S. $C_{23}H_{13}Cl_2Na_3O_9S$. (M_r 605). *1019600.* [1667-99-8].
Schultz No. 841.
Colour Index No. 43825.
Trisodium 5-[(3-carboxylato-5-methyl-4-oxocyclohexa-2,5-dien-1-ylidene)(2,6-dichloro-3-sulfonatophenyl)methyl]-2-hydroxy-3-methylbenzoate.
Brownish-black powder, soluble in water, slightly soluble in ethanol (96 per cent).

Chromic acid cleansing mixture. *1019700.*
A saturated solution of *chromium trioxide R* in *sulfuric acid R*.

Chromic potassium sulfate. $CrK(SO_4)_2,12H_2O$. (M_r 499.4). *1019800.* [7788-99-0]. Chrome alum.
Large, violet-red or black crystals, freely soluble in water, practically insoluble in ethanol (96 per cent).

Chromium(III) acetylacetonate. $C_{15}H_{21}CrO_6$. (M_r 349.3). *1172900.* [21679-31-2]. (*OC*-6-11)-Tris(2,4-pentanedionato-κ*O*, κ*O*′)chromium.

Chromium(III) trichloride hexahydrate. $[Cr(H_2O)_4Cl_2]Cl,2H_2O$. (M_r 266.5). *1104800.* [10060-12-5].
Dark green crystalline powder, hygroscopic.
Storage: protected from humidity and oxidising agents.

Chromium trioxide. CrO_3. (M_r 100.0). *1019900.* [1333-82-0].
Dark brownish-red needles or granules, deliquescent, very soluble in water.
Storage: in an airtight glass container.

Chromogenic substrate R1. *1020000.*
Dissolve *N*-α-benzyloxycarbonyl-D-arginyl-L-glycyl-L-arginine-4-nitroanilide dihydrochloride in *water R* to give a 0.003 M solution. Dilute in *tris(hydroxymethyl)aminomethane-EDTA buffer solution pH 8.4 R* to 0.0005 M before use.

Chromogenic substrate R2. *1020100.*
Dissolve D-phenylalanyl-L-pipecolyl-L-arginine-4-nitroanilide dihydrochloride in *water R* to give a 0.003 M solution. Dilute before use in titrating in *tris(hydroxymethyl)-aminomethane-EDTA buffer solution pH 8.4 R* to give a 0.0005 M solution.

Chromogenic substrate R3. *1149100.*
Dissolve D-valyl-leucyl-lysyl-4-nitroanilide dihydrochloride in *water R* to give a 0.003 M solution.

Chromogenic substrate R4. *1163100.*
Dissolve D-phenylalanyl-L-pipecolyl-L-arginine-4-nitroanilide dihydrochloride in *water R* to give a 0.008 M solution. Dilute to 0.0025 M with *phosphate buffer solution pH 8.5 R* before use.

Chromogenic substrate R5. *1163200.*
Dissolve *N*-benzoyl-L-isoleucyl-L-glutamyl-glycyl-L-arginine-4-nitroanilide hydrochloride in *water R* to give a 0.003 M solution.

Chromotrope II B. $C_{16}H_9N_3Na_2O_{10}S_2$. ($M_r$ 513.4). *1020200.* [548-80-1].

Schultz No. 67.

Colour Index No. 16575.
Disodium 4,5-dihydroxy-3-(4-nitrophenylazo)naphthalene-2,7-disulfonate.

Reddish-brown powder, soluble in water giving a yellowish-red colour, practically insoluble in ethanol (96 per cent).

Chromotrope II B solution. *1020201.*

A 0.05 g/L solution in *sulfuric acid R*.

Chromotropic acid, sodium salt. $C_{10}H_6Na_2O_8S_2,2H_2O$. ($M_r$ 400.3). *1020300.* [5808-22-0].

Schultz No. 1136.
Disodium 4,5-dihydroxynaphthalene-2,7-disulfonate dihydrate.
Disodium 1,8-dihydroxynaphthalene-3,6-disulfonate dihydrate.

A yellowish-white powder, soluble in water, practically insoluble in ethanol (96 per cent).

Chromotropic acid, sodium salt solution. *1020301.*

Dissolve 0.60 g of *chromotropic acid, sodium salt R* in about 80 mL of *water R* and dilute to 100 mL with the same solvent. Use this solution within 24 h.

Chromotropic acid-sulfuric acid solution. *1020302.*

Dissolve 5 mg of *chromotropic acids sodium salt R* in 10 mL of a mixture of 9 mL of *sulfuric acid R* and 4 mL of *water R*.

Chrysanthemin. $C_{21}H_{21}ClO_{11}$. (M_r 485.8). *1134800.* [7084-24-4].
Cyanidin 3-*O*-glucoside chloride. Kuromanin chloride.
2-(3,4-Dihydroxyphenyl)-3-(β-D-glucopyranosyl)oxy-5,7-dihydroxy-1-benzopyrylium chloride.

Reddish-brown crystalline powder, soluble in water and in ethanol (96 per cent).

Absorbance (*2.2.25*). A 0.01 g/L solution in a mixture of 1 volume of *hydrochloric acid R* and 999 volumes of *methanol R* shows an absorption maximum at 528 nm.

α-Chymotrypsin for peptide mapping. *1142400.*

α-Chymotrypsin of high purity, treated to eliminate tryptic activity.

Cinchonidine. $C_{19}H_{22}N_2O$. (M_r 294.4). *1020400.* [485-71-2].
(*R*)-(Quinol-4-yl)[(2*S*,4*S*,5*R*)-5-vinylquinuclidin-2-yl]methanol.

White or almost white, crystalline powder, very slightly soluble in water and in light petroleum, soluble in ethanol (96 per cent).

$[\alpha]_D^{20}$: – 105 to – 110, determined on a 50 g/L solution in *ethanol (96 per cent) R*.

mp: about 208 °C, with decomposition.

Storage: protected from light.

Cinchonine. $C_{19}H_{22}N_2O$. (M_r 294.4). *1020500.* [118-10-5].
(*S*)-(Quinol-4-yl)[(2*R*,4*S*,5*R*)-5-vinylquinuclidin-2-yl]methanol.

White or almost white, crystalline powder, very slightly soluble in water, sparingly soluble in ethanol (96 per cent) and in methanol.

$[\alpha]_D^{20}$: + 225 to + 230, determined on a 50 g/L solution in *ethanol (96 per cent) R*.

mp: about 263 °C.

Storage: protected from light.

Cineole. $C_{10}H_{18}O$. (M_r 154.3). *1020600.* [470-82-6]. 1,8-Cineole. Eucalyptol. 1,8-Epoxy-*p*-menthane.

Colourless liquid, practically insoluble in water, miscible with anhydrous ethanol.

d_{20}^{20}: 0.922 to 0.927.

n_D^{20}: 1.456 to 1.459.

Freezing point (*2.2.18*): 0 °C to 1 °C.

Distillation range (*2.2.11*): 174 °C to 177 °C.

Phenol. Shake 1 g with 20 mL of *water R*. Allow to separate and add to 10 mL of the aqueous layer 0.1 mL of *ferric chloride solution R1*. No violet colour develops.

Turpentine oil. Dissolve 1 g in 5 mL of *ethanol (90 per cent V/V) R*. Add dropwise freshly prepared *bromine water R*. Not more than 0.5 mL is required to give a yellow colour lasting for 30 min.

Residue on evaporation: maximum 0.05 per cent.

To 10.0 mL add 25 mL of *water R*, evaporate on a water-bath and dry the residue to constant mass at 100-105 °C.

Cineole used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405)*.

Test solution. The substance to be examined.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

1,4-Cineole. $C_{10}H_{18}O$. (M_r 154.3). *1142500.* [470-67-7].
1-Methyl-4-(1-methylethyl)-7-oxabicyclo[2.2.1]heptane.
1-Isopropyl-4-methyl-7-oxabicyclo[2.2.1]heptane.

Colourless liquid.

d_4^{20}: about 0.900.

n_D^{20}: about 1.445.

bp: about 173 °C.

Cinnamamide. C_9H_9NO. (M_r 147.2). *1154800.* [621-79-4].
(*E*)-3-Phenylprop-2-enamide.

White or almost white powder.

mp: about 149 °C.

***trans*-Cinnamic acid.** $C_9H_8O_2$. (M_r 148.2). *1159200.* [140-10-3].
trans-3-Phenylacrylic acid. (2*E*)-3-Phenylprop-2-enoic acid.

Colourless crystals, very slightly soluble in water, freely soluble in ethanol (96 per cent).

mp: 133 °C.

Cinnamic aldehyde. C_9H_8O. (M_r 132.2). *1020700.* [104-55-2].
3-Phenylpropenal.

Yellowish or greenish-yellow, oily liquid, slightly soluble in water, very soluble in ethanol (96 per cent).

d_{20}^{20}: 1.048 to 1.051.

n_D^{20}: about 1.620.

Storage: protected from light.

***trans*-Cinnamic aldehyde.** C_9H_8O. (M_r 132.2). *1124600.* [14371-10-9]. *(E)*-3-Phenylprop-2-enal.

trans-Cinnamic aldehyde used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Cassia oil (1496)*.

Content: minimum 99.0 per cent, calculated by the normalisation procedure.

Cinnamyl acetate. $C_{11}H_{12}O_2$. (M_r 176.2). *1124700.* [103-54-8].
3-Phenylprop-2-en-1-yl acetate.

n_D^{20}: about 1.542.

bp: about 262 °C.

Cinnamyl acetate used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Cassia oil (1496)*.

Content: minimum 99.0 per cent, calculated by the normalisation procedure.

Citral. $C_{10}H_{16}O$. (M_r 152.2). *1020800.* [5392-40-5]. Mixture of (2*E*)- and (2*Z*)-3,7-Dimethylocta-2,6-dienal.

Light yellow liquid, practically insoluble in water, miscible with ethanol (96 per cent) and with propylene glycol.

Chromatography. Thin-layer chromatography (*2.2.27*), using *silica gel* GF_{254} *R* as the coating substance: apply to the plate 10 µL of a 1 g/L solution in *toluene R*. Develop over a path of 15 cm using a mixture of 15 volumes of *ethyl acetate R* and 85 volumes of *toluene R*. Allow the plate to dry in air and examine in ultraviolet light at 254 nm. The chromatogram shows only one principal spot.

Citral used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Citronella oil (1609).*

Content of citral (neral + geranial): minimum 95.0 per cent, calculated by the normalisation procedure.

Citrated rabbit plasma. *1020900.*

Collect blood by intracardiac puncture from a rabbit kept fasting for 12 h, using a plastic syringe with a No. 1 needle containing a suitable volume of 38 g/L solution of *sodium citrate R* so that the final volume ratio of citrate solution to blood is 1: 9. Separate the plasma by centrifugation at 1500 *g* to 1800 *g* at 15 °C to 20 °C for 30 min.

Storage: at 0 °C to 6 °C; use within 4 h of collection.

Citric acid. *1021000.* [5949-29-1].

See *Citric acid monohydrate (0456).*
When used in the test for iron, it complies with the following additional requirement.

Dissolve 0.5 g in 10 mL of *water R*, add 0.1 mL of *thioglycollic acid R*, mix and make alkaline with *ammonia R*. Dilute to 20 mL with *water R*. No pink colour appears in the solution.

Citric acid, anhydrous. *1021200.* [77-92-9].

See *Anhydrous citric acid (0455).*

Citronellal. $C_{10}H_{18}O$. (M_r 154.3). *1113300.* [106-23-0]. 3,7-Dimethyl-6-octenal.

Very slightly soluble in water, soluble in ethanol (96 per cent).

d_{20}^{20}: 0.848 to 0.856.

n_D^{20}: about 1.446.

Citronellal used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Citronella oil (1609).*

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Citronellol. $C_{10}H_{20}O$. (M_r 156.3). *1134900.* [106-22-9]. 3,7-Dimethyloct-6-en-1-ol.

Clear, colourless liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: 0.857.

n_D^{20}: 1.456.

bp: 220 °C to 222 °C.

Citronellol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Citronella oil (1609).*

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Storage: in an airtight container, protected from light.

Citronellyl acetate. $C_{12}H_{22}O_2$. (M_r 198.3). *1135000.* [150-84-5]. 3,7-Dimethyl-6-octen-1-yl acetate.

d_{20}^{20}: 0.890.

n_D^{20}: 1.443.

bp: 229 °C.

Citronellyl acetate used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Citronella oil (1609).*

Content: minimum 97.0 per cent, calculated by the normalisation procedure.

Storage: in an airtight container, protected from light.

Citropten. $C_{11}H_{10}O_4$. (M_r 206.2). *1021300.* [487-06-9]. Limettin. 5,7-Dimethoxy-2*H*-1-benzopyran-2-one.

Needle-shaped crystals, practically insoluble in water and in light petroleum, freely soluble in acetone and in ethanol (96 per cent).

mp: about 145 °C.

Chromatography. Thin-layer chromatography (*2.2.27*), using *silica gel* GF_{254}*R* as the coating substance: apply to the plate 10 µL of a 1 g/L solution in *toluene R*. Develop over a path of 15 cm using a mixture of 15 volumes of *ethyl acetate R* and 85 volumes of *toluene R*. Allow the plate to dry in air and examine in ultraviolet light at 254 nm. The chromatogram obtained shows only one principal spot.

Clobetasol propionate. $C_{25}H_{32}ClFO_5$. (M_r 467.0). *1097700.* [25122-46-7]. 21-Chloro-9-fluoro-11β,17-dihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-propionate.

White or almost white crystalline powder, insoluble in water, soluble in ethanol (96 per cent) and in acetone.

$[\alpha]_D^{20}$: about + 104 (in dioxan).

mp: about 196 °C.

Coagulation factor V solution. *1021400.*

Coagulation factor V solution may be prepared by the following method or by any other method which excludes factor VIII.

Prepare the factor V reagent from fresh oxalated bovine plasma, by fractionation at 4 °C with a saturated solution of *ammonium sulfate R* prepared at 4 °C. Separate the fraction which precipitates between 38 per cent and 50 per cent of saturation, which contains factor V without significant contamination with factor VIII. Remove the ammonium sulfate by dialysis and dilute the solution with a 9 g/L solution of *sodium chloride R* to give a solution containing between 10 per cent and 20 per cent of the quantity of factor V present in fresh human normal plasma.

Assay of factor V. Prepare two dilutions of the preparation of factor V in *imidazole buffer solution pH 7.3 R* containing 1 volume of the preparation in 10 volumes and in 20 volumes of the buffer solution respectively. Test each dilution as follows: mix 0.1 mL of *plasma substrate deficient in factor V R*, 0.1 mL of the solution to be examined, 0.1 mL of *thromboplastin R* and 0.1 mL of a 3.5 g/L solution of *calcium chloride R* and measure the coagulation times, i.e. the interval between the moment at which the calcium chloride solution is added and the first indication of the formation of fibrin, which may be observed visually or by means of a suitable apparatus.

In the same manner, determine the coagulation time (in duplicate) of four dilutions of human normal plasma in *imidazole buffer solution pH 7.3 R*, containing respectively, 1 volume in 10 (equivalent to 100 per cent of factor V), 1 volume in 50 (20 per cent), 1 volume in 100 (10 per cent), and 1 volume in 1000 (1 per cent). Using two-way logarithmic paper plot the average coagulation times for each dilution of human plasma against the equivalent percentage of factor V and read the percentage of factor V for the two dilutions of the factor V solution by interpolation. The mean of the two results gives the percentage of factor V in the solution to be examined.

Storage: in the frozen state at a temperature not higher than −20 °C.

Cobalt chloride. $CoCl_2,6H_2O$. (M_r 237.9). *1021600.* [7791-13-1].
Red, crystalline powder or deep-red crystals, very soluble in water, soluble in ethanol (96 per cent).

Cobalt nitrate. $Co(NO_3)_2,6H_2O$. (M_r 291.0). *1021700.* [10026-22-9].
Small garnet-red crystals, very soluble in water.

Codeine. *1021800.* [6059-47-8].
See *Codeine (0076)*.

Codeine phosphate. *1021900.* [52-28-8].
See *Codeine phosphate hemihydrate (0074)*.

Congo red. $C_{32}H_{22}N_6Na_2O_6S_2$. ($M_r$ 697). *1022000.* [573-58-0].
Schultz No. 360.
Colour Index No. 22120.
Disodium (biphenyl-4,4′-diyl-bis-2,2′-azo)bis(1-aminonaphthalene-4-sulfonate).
Brownish-red powder, soluble in water.

Congo red paper. *1022002.*
Immerse strips of filter paper for a few minutes in *congo red solution R*. Allow to dry.

Congo red solution. *1022001.*
Dissolve 0.1 g of *congo red R* in a mixture of 20 mL of *ethanol (96 per cent) R* and *water R* and dilute to 100 mL with *water R*.
Test for sensitivity. To 0.2 mL of the congo red solution add 100 mL of *carbon dioxide-free water R* and 0.3 mL of *0.1 M hydrochloric acid*. The solution is blue. Not more than 0.3 mL of *0.1 M sodium hydroxide* is required to change the colour to pink.
Colour change: pH 3.0 (blue) to pH 5.0 (pink).

Coomassie blue. *1001400.* [3861-73-2].
See *acid blue 92 R*.

Coomassie blue solution. *1001401.*
See *acid blue 92 solution R*.

Coomassie staining solution. *1012201.*
A 1.25 g/L solution of *acid blue 83 R* in a mixture consisting of 1 volume of *glacial acetic acid R*, 4 volumes of *methanol R* and 5 volumes of *water R*. Filter.

Coomassie staining solution R1. *1173000.*
Dissolve 0.275 g of *brilliant blue R* in 200 mL of *methanol R*. Stir until complete dissolution of the crystals (for about 2 h). Add 750 mL of *water R* and 50 mL of *glacial acetic acid R*. Stir overnight (for at least 16 h); filter.

Copper. Cu. (A_r 63.55). *1022100.* [7440-50-8].
Cleaned foil, turnings, wire or powder of the pure metal of electrolytic grade.

Copper acetate. $C_4H_6CuO_4,H_2O$. (M_r 199.7). *1022200.* [142-71-2].
Blue-green crystals or powder, freely soluble in boiling water, soluble in water and in ethanol (96 per cent), slightly soluble in glycerol (85 per cent).

Copper edetate solution. *1022300.*
To 2 mL of a 20 g/L solution of *copper acetate R* add 2 mL of *0.1 M sodium edetate* and dilute to 50 mL with *water R*.

Copper nitrate. $Cu(NO_3)_2,3H_2O$. (M_r 241.6). *1022400.* [10031-43-3]. Chloride dinitrate trihydrate.
Dark blue crystals, hygroscopic, very soluble in water giving a strongly acid reaction, freely soluble in ethanol (96 per cent) and in dilute nitric acid.
Storage: in an airtight container.

Copper sulfate. $CuSO_4,5H_2O$. (M_r 249.7). *1022500.* [7758-99-8].
Blue powder or deep-blue crystals, slowly efflorescent, very soluble in water, slightly soluble in ethanol (96 per cent).

Copper sulfate solution. *1022501.*
A 125 g/L solution.

Copper tetrammine, ammoniacal solution of. *1022600.*
Dissolve 34.5 g of *copper sulfate R* in 100 mL of *water R* and, whilst stirring, add dropwise *concentrated ammonia R* until the precipitate which forms dissolves completely. Keeping the temperature below 20 °C, add dropwise with continuous shaking 30 mL of *strong sodium hydroxide solution R*. Filter through a sintered-glass filter (40) (*2.1.2*), wash with *water R* until the filtrate is clear and take up the precipitate with 200 mL of *concentrated ammonia R*. Filter through a sintered-glass filter (*2.1.2*) and repeat the filtration to reduce the residue to a minimum.

Cortisone. $C_{21}H_{28}O_5$. (M_r 360.4). *1175000.* [53-06-5].
Content: minimum 95.0 per cent.
mp: 223-228 °C.

Cortisone acetate. *1097800.* [50-04-4].
See *Cortisone acetate (0321)*.

Coumaphos. $C_{14}H_{16}ClO_5PS$. (M_r 362.8). *1124800.* [56-72-4].
mp: 91 °C to 92 °C.
A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

***o*-Coumaric acid.** $C_9H_8O_3$. (M_r 164.2). *1157400.* [614-60-8]. (*E*)-2-Hydroxycinnamic acid. (2*E*)-3-(2-Hydroxyphenyl)prop-2-enoic acid.
White or almost white powder.
mp: about 217 °C.

***p*-Coumaric acid.** $C_9H_8O_3$. (M_r 164.2). *1157500.* [7400-08-0]. 4-Hydroxycinnamic acid. 3-(4-Hydroxyphenyl)-prop-2-enoic acid.
White or almost white needles, practically insoluble in water, soluble in acetone and in methanol.
mp: 214 °C to 217 °C.
p-Coumaric acid used in the assay in Nettle leaf (1897) complies with the following additional tests.
Loss on drying (*2.2.32*): maximum 5.0 per cent, determined on 0.200 g by drying in an oven at 105 °C for 2 h.
Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Nettle leaf (1897)*.
Content: minimum 95 per cent, calculated by the normalisation procedure.

Coumarin. $C_9H_6O_2$. (M_r 146.1). *1124900.* [91-64-5]. 2*H*-Chromen-2-one. 2*H*-1-Benzopyran-2-one.
Colourless, crystalline powder or orthorhombic or rectangular crystals, very soluble in boiling water, soluble in ethanol (96 per cent). It dissolves in solutions of alkali hydroxides.
mp: 68 °C to 70 °C.
Coumarin used in gas chromatography complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Cassia oil (1496)*.
Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Cresol. C_7H_8O. (M_r 108.1). *1022700.* [95-48-7]. *o*-Cresol. 2-Methylphenol.
Crystals or a super-cooled liquid becoming dark on exposure to light and air, miscible with anhydrous ethanol, soluble in about 50 parts of water and soluble in solutions of alkali hydroxides.
d_{20}^{20}: about 1.05.

n_D^{20}: 1.540 to 1.550.

bp: about 190 °C.

Freezing point (*2.2.18*): minimum 30.5 °C.

Residue on evaporation: maximum 0.1 per cent *m/m*, determined by evaporating on a water-bath and drying in an oven at 100-105 °C.

Storage: protected from light, moisture and oxygen.

Distil before use.

m-Cresol. *1177100.* [108-39-4].

See *metacresol (2077)*.

p-Cresol. C_7H_8O. (M_r 108.1). *1153100.* [106-44-5].
4-Methylphenol.

Colourless or white or almost white crystals or crystalline mass.

d_{20}^{20}: about 1.02.

bp: about 202 °C.

m-Cresol purple. $C_{21}H_{18}O_5S$. (M_r 382.44). *1121700.* [2303-01-7].
m-Cresolsulfonphthalein.

Olive-green, crystalline powder, slightly soluble in water, soluble in ethanol (96 per cent), in glacial acetic acid and in methanol.

m-Cresol purple solution. *1121701.*

Dissolve 0.1 g of *m-cresol purple R* in 13 mL of *0.01 M sodium hydroxide*, dilute to 100 mL with *water R* and mix.

Colour change: pH 1.2 (red) to pH 2.8 (yellow); pH 7.4 (yellow) to pH 9.0 (purple).

Cresol red. $C_{21}H_{18}O_5S$. (M_r 382.4). *1022800.* [1733-12-6].
Cresolsulfonphthalein. 4,4′-(3*H*-2,1-Benzoxathiol-3-ylidene)bis-(2-methylphenol) *S*,*S*-dioxide.

A reddish-brown crystalline powder, slightly soluble in water, soluble in ethanol (96 per cent) and in dilute solutions of alkali hydroxides.

Cresol red solution. *1022801.*

Dissolve 0.1 g of *cresol red R* in a mixture of 2.65 mL of *0.1 M sodium hydroxide* and 20 mL of *ethanol (96 per cent) R* and dilute to 100 mL with *water R*.

Test for sensitivity. A mixture of 0.1 mL of the cresol red solution and 100 mL of *carbon dioxide-free water R* to which 0.15 mL of *0.02 M sodium hydroxide* has been added is purple-red. Not more than 0.15 mL of *0.02 M hydrochloric acid* is required to change the colour to yellow.

Colour change: pH 7.0 (yellow) to pH 8.6 (red).

Crystal violet. $C_{25}H_{30}ClN_3$. (M_r 408.0). *1022900.* [548-62-9].

Schultz No. 78.

Colour Index No. 42555.
Hexamethyl-pararosanilinium chloride.

Dark-green powder or crystals, soluble in water and in ethanol (96 per cent).

Crystal violet solution. *1022901.*

Dissolve 0.5 g of *crystal violet R* in *anhydrous acetic acid R* and dilute to 100 mL with the same solvent.

Test for sensitivity. To 50 mL of *anhydrous acetic acid R* add 0.1 mL of the crystal violet solution. On addition of 0.1 mL of *0.1 M perchloric acid* the bluish-purple solution turns bluish-green.

Cupric chloride. $CuCl_2,2H_2O$. (M_r 170.5). *1023000.* [10125-13-0]. Cupric chloride dihydrate.

Greenish-blue powder or crystals, deliquescent in moist air, efflorescent in dry air, freely soluble in water, in ethanol (96 per cent) and in methanol, sparingly soluble in acetone.

Storage: in an airtight container.

Cupri-citric solution. *1023100.*

Dissolve 25 g of *copper sulfate R*, 50 g of *citric acid R* and 144 g of *anhydrous sodium carbonate R* in *water R* and dilute to 1000 mL with the same solvent.

Cupri-citric solution R1. *1023200.*

Dissolve 25 g of *copper sulfate R*, 50 g of *citric acid R* and 144 g of *anhydrous sodium carbonate R* in *water R* and dilute to 1000 mL with the same solvent.

Adjust the solution so that it complies with the following requirements.

a) To 25.0 mL add 3 g of *potassium iodide R*. Add 25 mL of a 25 per cent *m/m* solution of *sulfuric acid R* with precaution and in small quantities. Titrate with *0.1 M sodium thiosulfate* using 0.5 mL of *starch solution R*, added towards the end of the titration, as indicator.

24.5 mL to 25.5 mL of *0.1 M sodium thiosulfate* is used in the titration.

b) Dilute 10.0 mL to 100.0 mL with *water R* and mix. To 10.0 mL of the solution, add 25.0 mL of *0.1 M hydrochloric acid* and heat for 1 h on a water-bath. Cool, adjust with *water R* to the initial volume and titrate with *0.1 M sodium hydroxide*, using 0.1 mL of *phenolphthalein solution R1* as indicator.

5.7 mL to 6.3 mL of *0.1 M sodium hydroxide* is used in the titration.

c) Dilute 10.0 mL to 100.0 mL with *water R* and mix. Titrate 10.0 mL of the solution with *0.1 M hydrochloric acid*, using 0.1 mL of *phenolphthalein solution R1* as indicator.

6.0 mL to 7.5 mL of *0.1 M hydrochloric acid* is used in the titration.

Cupriethylenediamine hydroxide solution. *3008700.* [14552-35-3].

The molar ratio of ethylenediamine to copper is 2.00 ± 0.04.

This solution is commercially available.

Cupri-tartaric solution. *1023300.*

Solution A. Dissolve 34.6 g of *copper sulfate R* in *water R* and dilute to 500 mL with the same solvent.

Solution B. Dissolve 173 g of *sodium potassium tartrate R* and 50 g of *sodium hydroxide R* in 400 mL of *water R*. Heat to boiling, allow to cool and dilute to 500 mL with *carbon dioxide-free water R*.

Mix equal volumes of the 2 solutions immediately before use.

Cupri-tartaric solution R2. *1023302.*

Add 1 mL of a solution containing 5 g/L of *copper sulfate R* and 10 g/L of *potassium tartrate R* to 50 mL of *sodium carbonate solution R1*. Prepare immediately before use.

Cupri-tartaric solution R3. *1023303.*

Prepare a solution containing 10 g/L of *copper sulfate R* and 20 g/L of *sodium tartrate R*. To 1.0 mL of the solution add 50 mL of *sodium carbonate solution R2*. Prepare immediately before use.

Cupri-tartaric solution R4. *1023304.*

Solution A. 150 g/L *copper sulfate R*.

Solution B. Dissolve 2.5 g of *anhydrous sodium carbonate R*, 2.5 g of *potassium sodium tartrate R*, 2.0 g of *sodium hydrogen carbonate R*, and 20.0 g of *anhydrous sodium sulfate R* in *water R* and dilute to 100 mL with the same solvent.

Mix 1 part of solution A with 25 parts of solution B immediately before use.

Curcumin. $C_{21}H_{20}O_6$. (M_r 368.4). *1023500.* [458-37-7].
1,7-bis(4-Hydroxy-3-methoxyphenyl)hepta-1,6-diene-3,5-dione.

Orange-brown, crystalline powder, practically insoluble in water, soluble in glacial acetic acid.

mp: about 183 °C.

Cyanoacetic acid. $C_3H_3NO_2$. (M_r 85.1). *1097900.* [372-09-8].
White or yellowish-white, hygroscopic crystals, very soluble in water.
Storage: in an airtight container.

Cyanocobalamin. *1023600.* [68-19-9].
See *Cyanocobalamin (0547).*

Cyanogen bromide solution. *1023700.* [506-68-3].
Add dropwise, with cooling *0.1 M ammonium thiocyanate* to *bromine water R* until the yellow colour disappears. Prepare immediately before use.

Cyanoguanidine. $C_2H_4N_4$. (M_r 84.1). *1023800.* [461-58-5].
Dicyandiamide. 1-Cyanoguanidine.
White or almost white, crystalline powder, sparingly soluble in water and in ethanol (96 per cent), practically insoluble in methylene chloride.
mp: about 210 °C.

α-Cyclodextrin. $C_{36}H_{60}O_{30}$. (M_r 972). *1176200.* [10016-20-3].
Cyclohexakis-(1→4)-(α-D-glucopyranosyl). Cyclomaltohexaose. Alfadex.

β-Cyclodextrin for chiral chromatography, modified. *1154600.*
30 per cent of 2,3-di-*O*-ethyl-6-*O*-*tert*-butyldimethylsilyl-β-cyclodextrin dissolved in *poly(dimethyl)(85)(diphenyl)(15)siloxane R*.

β-Cyclodextrin for chiral chromatography, modified R1. *1160700.*
30 per cent of 2,3-di-*O*-acetyl-6-*O*-*tert*-butylsilyl-β-cyclodextrin dissolved in *poly(dimethyl)(85)(diphenyl)(15)siloxane R*.

Cyclohexane. C_6H_{12}. (M_r 84.2). *1023900.* [110-82-7].
Clear, colourless, flammable liquid, practically insoluble in water, miscible with organic solvents.
d_{20}^{20}: about 0.78.
bp: about 80.5 °C.
Cyclohexane used in spectrophotometry complies with the following additional test.
Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 45 per cent at 220 nm, 70 per cent at 235 nm, 90 per cent at 240 nm, 98 per cent at 250 nm.

Cyclohexane R1. *1023901.*
Complies with the requirements prescribed for *cyclohexane R* with the following additional requirement.
The fluorescence, measured at 460 nm, under illumination with an excitant light beam at 365 nm, is not more intense than that of a solution containing 0.002 ppm of *quinine R* in *0.05 M sulfuric acid*.

Cyclohexylamine. $C_6H_{13}N$. (M_r 99.2). *1024000.* [108-91-8].
Colourless liquid, soluble in water, miscible with usual organic solvents.
n_D^{20}: about 1.460.
bp: 134 °C to 135 °C.

Cyclohexylenedinitrilotetra-acetic acid. $C_{14}H_{22}N_2O_8,H_2O$. (M_r 364.4). *1024100. trans*-Cyclohexylene-1,2-dinitrilo-*N,N,N',N'*-tetra-acetic acid.
White or almost white, crystalline powder.
mp: about 204 °C.

Cyclohexylmethanol. $C_7H_{14}O$. (M_r 114.2). *1135200.* [100-49-2].
Cyclohexylcarbinol.
Liquid with a slight odour of camphor, soluble in ethanol (96 per cent).
n_D^{25}: about 1.464.
bp: about 185 °C.

3-Cyclohexylpropionic acid. $C_9H_{16}O_2$. (M_r 156.2). *1119200.* [701-97-3].
Clear liquid.
d_{20}^{20}: about 0.998.
n_D^{20}: about 1.4648.
bp: about 130 °C.

Cyhalothrin. $C_{23}H_{19}ClF_3NO_3$. (M_r 449.9). *1125000.* [91465-08-6].
bp: 187 °C to 190 °C.
mp: about 49 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

***p*-Cymene.** $C_{10}H_{14}$. (M_r 134.2). *1113400.* [99-87-6].
1-Isopropyl-4-methylbenzene.
Colourless liquid, practically insoluble in water, soluble in ethanol (96 per cent).
d_{20}^{20}: about 0.858.
n_D^{20}: about 1.4895.
bp: 175 °C to 178 °C.
p-Cymene used in gas chromatography complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*
Test solution. The substance to be examined.
Content: minimum 96.0 per cent, calculated by the normalisation procedure.

Cynarin. $C_{25}H_{24}O_{12}$. (M_r 516.4). *1159300.* [30964-13-7].
(1α,3α,4α,5β)-1,3-Bis[[3-(3,4-Dihydroxyphenyl)-1-oxo-2-propenyl]oxy]-4,5-dihydroxycyclohexanecarboxylic acid.
White or almost white amorphous mass, odourless.

Cypermethrin. $C_{22}H_{19}Cl_2NO_3$. (M_r 416.3). *1125100.* [52315-07-8].
bp: 170 °C to 195 °C.
mp: 60 °C to 80 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

L-Cysteine. $C_3H_7NO_2S$. (M_r 121.1). *1024200.* [52-90-4].
Powder, freely soluble in water, in ethanol (96 per cent) and in acetic acid, practically insoluble in acetone.

Cysteine hydrochloride. *1024300.* [7048-04-6].
See *Cysteine hydrochloride monohydrate (0895).*

L-Cystine. $C_6H_{12}N_2O_4S_2$. (M_r 240.3). *1024400.* [56-89-3].
White or almost white, crystalline powder, practically insoluble in water and in ethanol (96 per cent). It dissolves in dilute solutions of alkali hydroxides.
$[\alpha]_D^{20}$: – 218 to – 224, determined in *1 M hydrochloric acid*.
mp: 250 °C, with decomposition.

Cytosine. $C_4H_5N_3O$. (M_r 111.1). *1160800.* [71-30-7].
Content: minimum 95.0 per cent.

Daidzein. $C_{15}H_{10}O_4$. (M_r 254.2). *1178400.* [486-66-8].
7-Hydroxy-3-(4-hydroxyphenyl)-4*H*-1-benzopyran-4-one.

Daidzin. $C_{21}H_{20}O_9$. (M_r 416.4). *1178300.* [552-66-9]. 7-(β-D-Glucopyranosyloxy)-3-(4-hydroxyphenyl)-4*H*-1-benzopyran-4-one.

Dantron. $C_{14}H_8O_4$. (M_r 240.2). *1024500.* [117-10-2]. 1,8-Dihydroxyanthraquinone. 1,8-Dihydroxyanthracene-9,10-dione.
Crystalline orange powder, practically insoluble in water, slightly soluble in ethanol (96 per cent), soluble in solutions of alkali hydroxides.
mp: about 195 °C.
Dantron used in the sesquiterpenic acids assay in Valerian root (0453) complies with the following additional tests.

$A_{1\,cm}^{1\%}$: 355 to 375, determined at 500 nm in *1 M potassium hydroxide*.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Valerian Root (0453)* at the concentration of the reference solution.

Content: minimum 95 per cent, calculated by the normalisation procedure.

***o,p′*-DDD.** $C_{14}H_{10}Cl_4$. (M_r 320.0). *1125200*. [53-19-0]. 1-(2-Chlorophenyl)-1-(4-chlorophenyl)-2,2-dichloroethane.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

***p,p′*-DDD.** $C_{14}H_{10}Cl_4$. (M_r 320.0). *1125300*. [72-54-8]. 1,1-bis(4-Chlorophenyl)-2,2-dichloroethane.

bp: about 193 °C.

mp: about 109 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

***o,p′*-DDE.** $C_{14}H_8Cl_4$. (M_r 318.0). *1125400*. [3424-82-6]. 1-(2-Chlorophenyl)-1-(4-chlorophenyl)-2,2-dichloroethylene. A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

***p,p′*-DDE.** $C_{14}H_8Cl_4$. (M_r 318.0). *1125500*. [72-55-9]. 1,1-bis(4-Chlorophenyl)-2,2-dichloroethylene.

bp: 316 °C to 317 °C.

mp: 88 °C to 89 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

***o,p′*-DDT.** $C_{14}H_9Cl_5$. (M_r 354.5). *1125600*. [789-02-6]. 1-(2-Chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethane.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

***p,p′*-DDT.** $C_{14}H_9Cl_5$. (M_r 354.5). *1125700*. [50-29-3]. 1,1-bis(4-Chlorophenyl)-2,2,2-trichloroethane.

bp: about 260 °C.

mp: 108 °C to 109 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Decanal. $C_{10}H_{20}O$. (M_r 156.3). *1149200*. [112-31-2]. Decyl aldehyde.

Oily, colourless liquid, with a characteristic odour of orange, practically insoluble in water, soluble in chloroform.

d_4^{20}: 0.825 to 0.829.

n_D^{20}: 1.420 to 1.430.

bp: 207 °C to 209 °C.

Decanal used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Sweet orange oil (1811)*.

Content: minimum 99 per cent, calculated by the normalisation procedure.

Decane. $C_{10}H_{22}$. (M_r 142.3). *1024600*. [124-18-5].

Colourless liquid, practically insoluble in water.

n_D^{20}: about 1.411.

bp: about 174 °C.

Decanol. $C_{10}H_{22}O$. (M_r 158.3). *1024700*. [112-30-1]. *n*-Decyl alcohol.

Viscous liquid, solidifying at about 6 °C, practically insoluble in water, soluble in ethanol (96 per cent).

n_D^{20}: about 1.436.

bp: about 230 °C.

Deltamethrin. $C_{22}H_{19}Br_2NO_3$. (M_r 505.2). *1125800*. [52918-63-5].

bp: about 300 °C.

mp: about 98 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Demeclocycline hydrochloride. *1145600*.

See *Demeclocycline hydrochloride (0176)*.

Demethylflumazenil. $C_{14}H_{12}FN_3O_3$. (M_r 289.3). *1149300*. [79089-72-8]. Ethyl 8-fluoro-6-oxo-5,6-dihydro-4*H*-imidazo[1,5-*a*][1,4]benzodiazepine-3-carboxylate.

Colourless needles, soluble in dimethyl sulfoxide and in hot methanol.

mp: about 288 °C.

2-Deoxy-D-ribose. $C_5H_{10}O_4$. (M_r 134.1). *1163900*. [533-67-5]. Thyminose. 2-Deoxy-D-*erythro*-pentose.

2′-Deoxyuridine. $C_9H_{12}N_2O_5$. (M_r 228.2). *1024800*. [951-78-0]. 1-(2-Deoxy-β-d-*erythro*-pentofuranosyl)-1*H*,3*H*-pyrimidine-2,4-dione.

mp: about 165 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Idoxuridine (0669)*: apply 5 µL of a 0.25 g/L solution; the chromatogram shows only one principal spot.

4-Desoxypyridoxine hydrochloride. $C_8H_{12}NO_2Cl$. (M_r 189.6). *1175500*. [148-51-6]. 5-(Hydroxymethyl)-2,4-dimethylpyridin-3-ol.

Destaining solution. *1012202*.

A mixture consisting of 1 volume of *glacial acetic acid R*, 4 volumes of *methanol R* and 5 volumes of *water R*.

Deuterated acetic acid. $C_2{}^2H_4O_2$. (M_r 64.1). *1101100*. [1186-52-3]. Tetradeuteroacetic acid. Acetic-d_3 acid-*d*.

Degree of deuteration: minimum 99.7 per cent.

d_{20}^{20}: about 1.12.

n_D^{20}: about 1.368.

bp: about 115 °C.

mp: about 16 °C.

Deuterated acetone. $C_3{}^2H_6O$. (M_r 64.1). *1024900*. [666-52-4]. Acetone-d_6. ($^2H_6$)-Acetone.

Degree of deuteration: minimum 99.5 per cent.

Clear, colourless liquid, miscible with water, with dimethylformamide, with anhydrous ethanol and with methanol.

d_{20}^{20}: about 0.87.

n_D^{20}: about 1.357.

bp: about 55 °C.

Water and deuterium oxide. Not more than 0.1 per cent.

Deuterated acetonitrile. $C_2{}^2H_3N$. (M_r 44.1). *1173100*. [2206-26-0].

Degree of deuteration: minimum 99.8 per cent.

Clear, colourless liquid, miscible with water, with acetone and with methanol.

d_{20}^{20}: about 0.78.

n_D^{20}: about 1.344.

Deuterated chloroform. C^2HCl_3. (M_r 120.4). *1025000*. [865-49-6]. (^2H)-Chloroform. Chloroform-*d*.

Degree of deuteration: minimum 99.7 per cent.

Clear, colourless liquid, practically insoluble in water, miscible with acetone and with ethanol (96 per cent). It may be stabilised over silver foil.

d_{20}^{20}: about 1.51.

n_D^{20}: about 1.445.

bp: about 60 °C.

Water and deuterium oxide: maximum 0.05 per cent.

Deuterated dimethyl sulfoxide. $C_2{}^2H_6OS$. (M_r 84.2). *1025100.* [2206-27-1]. ($^2H_6$)-Dimethyl sulfoxide. Dimethyl sulfoxide-d_6.

Degree of deuteration: minimum 99.8 per cent.

Very hygroscopic liquid, practically colourless, viscous, soluble in water, in acetone and in anhydrous ethanol.

d_{20}^{20}: about 1.18.

mp: about 20 °C.

Water and deuterium oxide: maximum 0.1 per cent.

Storage: in an airtight container.

Deuterated methanol. C^2H_4O. (M_r 36.1). *1025200.* [811-98-3]. (^2H)-Methanol. Methanol-*d*.

Degree of deuteration: minimum 99.8 per cent.

Clear, colourless liquid miscible with water, with ethanol (96 per cent) and with methylene chloride.

d_{20}^{20}: about 0.888.

n_D^{20}: about 1.326.

bp: 65.4 °C.

Deuterated sodium trimethylsilylpropionate. $C_6H_9{}^2H_4NaO_2Si$. (M_r 172.3). *1179100.* [24493-21-8]. Sodium 3-(trimethylsilyl)(2,2,3,3-$^2H_4$)propionate. TSP-d_4.

Degree of deuteration: minimum 98 per cent.

White or almost white powder.

Deuterium chloride. ^2HCl. (M_r 37.47). *1178800.* [7698-05-7]. Deuterated hydrochloric acid.

Gas.

Degree of deuteration: minimum 99 per cent.

Caution: *toxic*.

Deuterium chloride solution. *1178801.*

Dilute 1 mL of *deuterium chloride R* (38 per cent *m/m*) with 5 mL of *deuterium oxide R*.

Deuterium oxide. ^2H_2O. (M_r 20.03). *1025300.* [7789-20-0]. Deuterated water.

Degree of deuteration: minimum 99.7 per cent.

d_{20}^{20}: about 1.11.

n_D^{20}: about 1.328.

bp: about 101 °C.

Deuterium oxide R1. ^2H_2O. (M_r 20.03). *1025301.* [7789-20-0]. Deuterated water.

Degree of deuteration: minimum 99.95 per cent.

Developer solution. *1122500.*

Dilute 2.5 mL of a 20 g/L solution of *citric acid R* and 0.27 mL of *formaldehyde R* to 500.0 mL with *water R*.

Dextran for chromatography, cross-linked R2. *1025500.*

Bead-form dextran with a fraction range suitable for the separation of peptides and proteins with relative molecular masses of 15×10^2 to 30×10^3. When dry, the beads have a diameter of 20-80 µm.

Dextran for chromatography, cross-linked R3. *1025600.*

Bead-form dextran with a fraction range suitable for the separation of peptides and proteins with relative molecular masses of 4×10^3 to 15×10^4. When dry, the beads have a diameter of 40-120 µm.

Dextrose. *1025700.* [50-99-7].

See *glucose R*.

3,3′-Diaminobenzidine tetrahydrochloride. $C_{12}H_{18}Cl_4N_4$, $2H_2O$. (M_r 396.1). *1098000.* [7411-49-6]. 3,3′,4,4′-Biphenyl-tetramine.

Almost white or slightly pink powder, soluble in water.

mp: about 280 °C, with decomposition.

Diammonium 2,2′-azinobis(3-ethylbenzothiazoline-6-sulfonate). $C_{18}H_{24}N_6O_6S_4$. (M_r 548.7). *1153000.* [30931-67-0]. ABTS. Diammonium 2,2′-(diazanediylidene)bis[3-ethyl-2,3-dihydrobenzothiazole-6-sulfonate].

Chromogenic substrate suitable for use in ELISA procedures.

Green tablets, freely soluble in water.

pH (*2.2.3*): 4.2 to 5.8 for a 0.1 g/L solution.

Diatomaceous earth. *1025900.* [91053-39-3].

White or almost white, fine granular powder, made up of siliceous frustules of fossil diatoms or of debris of fossil diatoms, practically insoluble in water and in ethanol (96 per cent).

The substance may be identified by microscopic examination with a magnification of × 500.

Diatomaceous earth for gas chromatography. *1026000.*

White or almost white, fine granular powder, made up of siliceous frustules of fossil diatoms or of debris of fossil diatoms, practically insoluble in water and in ethanol (96 per cent). The substance may be identified by microscopic examination with a magnification of × 500. The substance is purified by treating with *hydrochloric acid R* and washing with *water R*.

Particle size: maximum 5 per cent is retained on a sieve No. 180. Maximum 10 per cent passes a sieve No. 125.

Diatomaceous earth for gas chromatography R1. *1026100.*

White or almost white, fine granular powder, made up of siliceous frustules of fossil diatoms or of debris of fossil diatoms, practically insoluble in water and in ethanol (96 per cent). The substance may be identified by microscopic examination with a magnification of × 500. The substance is purified by treating with *hydrochloric acid R* and washing with *water R*.

Particle size. Maximum 5 per cent is retained on a sieve No. 250. Maximum 10 per cent passes a sieve No. 180.

Diatomaceous earth for gas chromatography R2. *1026200.*

White or almost white, fine granular powder with a specific surface area of about 0.5 m^2/g, made up of siliceous frustules of fossil diatoms or of debris of fossil diatoms, practically insoluble in water and in ethanol (96 per cent). The substance may be identified by microscopic examination with a magnification of × 500. The substance is purified by treating with *hydrochloric acid R* and washing with *water R*.

Particle size. Maximum 5 per cent is retained on a sieve No. 180. Maximum 10 per cent passes a sieve No. 125.

Diatomaceous earth for gas chromatography, silanised. *1026300.*

Diatomaceous earth for gas chromatography R silanised with dimethyldichlorosilane or other suitable silanising agents.

Diatomaceous earth for gas chromatography, silanised R1. *1026400.*

Prepared from crushed pink firebrick and silanised with dimethyldichlorosilane or other suitable silanising agents. The substance is purified by treating with *hydrochloric acid R* and washing with *water R*.

Diazinon. $C_{12}H_{21}N_2O_3PS$. (M_r 304.3). *1125900.* [333-41-5].

bp: about 306 °C.

A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

Diazobenzenesulfonic acid solution R1. *1026500.*

Dissolve 0.9 g of *sulfanilic acid R* in a mixture of 30 mL of *dilute hydrochloric acid R* and 70 mL of *water R*. To 3 mL of the solution add 3 mL of a 50 g/L solution of *sodium nitrite R*. Cool in an ice-bath for 5 min, add 12 mL of the sodium nitrite

solution and cool again. Dilute to 100 mL with *water R* and keep the reagent in an ice-bath. Prepare extemporaneously but allow to stand for 15 min before use.

Dibutylamine. $C_8H_{19}N$. (M_r 129.3). *1126000.* [111-92-2]. *N*-Butylbutan-1-amine.

Colourless liquid.

n_D^{20}: about 1.417.

bp: about 159 °C.

Dibutylammonium phosphate for ion-pairing. *1168800.*

A colourless solution of 10 per cent to 15 per cent *V/V* of di-*n*-butylamine and 12 per cent to 17 per cent *V/V* of phosphoric acid in water, suitable for ion-pairing in liquid chromatography.

Dibutyl ether. $C_8H_{18}O$. (M_r 130.2). *1026700.* [142-96-1].

Colourless, flammable liquid, practically insoluble in water, miscible with anhydrous ethanol.

d_{20}^{20}: about 0.77.

n_D^{20}: about 1.399.

Do not distil if the dibutyl ether does not comply with the test for peroxides.

Peroxides. Place 8 mL of *potassium iodide and starch solution R* in a 12 mL ground-glass-stoppered cylinder about 1.5 cm in diameter. Fill completely with the substance to be examined, shake vigorously and allow to stand protected from light for 30 min. No colour is produced.

The name and concentration of any added stabiliser are stated on the label.

Dibutyl phthalate. $C_{16}H_{22}O_4$. (M_r 278.3). *1026800.* [84-74-2]. Dibutyl benzene-1,2-dicarboxylate.

Clear, colourless or faintly coloured, oily liquid, very slightly soluble in water, miscible with acetone and with ethanol (96 per cent).

d_{20}^{20}: 1.043 to 1.048.

n_D^{20}: 1.490 to 1.495.

Dicarboxidine hydrochloride. $C_{20}H_{26}Cl_2N_2O_6$. (M_r 461.3). *1026900.* [56455-90-4]. 4,4′-[(4,4′-Diaminobiphenyl-3,3′-diyl)dioxy]dibutanoic acid dihydrochloride.

Dichlofenthion. $C_{10}H_{13}Cl_2O_3PS$. (M_r 315.2). *1126100.* [97-17-6].

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Dichloroacetic acid. $C_2H_2Cl_2O_2$. (M_r 128.9). *1027000.* [79-43-6].

Colourless liquid, miscible with water and ethanol (96 per cent).

d_{20}^{20}: about 1.566.

n_D^{20}: about 1.466.

bp: about 193 °C.

Dichloroacetic acid solution. *1027001.*

Dilute 67 mL of *dichloroacetic acid R* to 300 mL with *water R* and neutralise to *blue litmus paper R* using *ammonia R*. Cool, add 33 mL of *dichloroacetic acid R* and dilute to 600 mL with *water R*.

3,5-Dichloroaniline. $C_6H_5Cl_2N$. (M_r 162.0). *1177800.* [626-43-7]. 3,5-dichlorophenylamine.

mp: 46 °C to 52 °C.

Dichlorobenzene. $C_6H_4Cl_2$. (M_r 147.0). *1027100.* [95-50-1]. 1,2-Dichlorobenzene.

Colourless, oily liquid, practically insoluble in water, soluble in anhydrous ethanol.

d_{20}^{20}: about 1.31.

bp: about 180 °C.

2,3-Dichloro-5,6-dicyanobenzoquinone. $C_8Cl_2N_2O_2$. (M_r 227.0). *1153600.* [84-58-2]. 4,5-Dichloro-3,6-dioxo-cyclohexa-1,4-diene-1,2-dicarbonitrile.

Yellow or orange crystals, soluble in dioxan and in acetic acid, slightly soluble in methylene chloride. It decomposes in water.

mp: about 214 °C.

Storage: at a temperature of 2 °C to 8 °C.

(*S*)-3,5-Dichloro-2,6-dihydroxy-*N*-[(1-ethylpyrrolidin-2-yl)methyl]benzamide hydrobromide. $C_{14}H_{19}BrCl_2N_2O_3$. (M_r 414.1). *1142600.* [113310-88-6].

White or almost white, crystalline powder.

$[\alpha]_D^{22}$: + 11.4, determined on a 15.0 g/L solution in *anhydrous ethanol R*.

mp: about 212 °C.

Dichlorofluorescein. $C_{20}H_{10}Cl_2O_5$. (M_r 401.2). *1027200.* [76-54-0]. 2,7-Dichlorofluorescein. 2-(2,7-Dichloro-6-hydroxy-3-oxo-3*H*-xanthen-9-yl)benzoic acid.

Yellowish-brown or yellow-orange powder, slightly soluble in water, freely soluble in ethanol (96 per cent) and in dilute solutions of alkali hydroxides giving a solution showing a yellowish-green fluorescence.

2,6-Dichlorophenol. $C_6H_4Cl_2O$. (M_r 163.0). *1177600.* [87-65-0].

mp: 64 °C to 66 °C.

Dichlorophenolindophenol, sodium salt. $C_{12}H_6Cl_2NNaO_2$,$2H_2O$. (M_r 326.1). *1027300.* [620-45-1]. The sodium derivative of 2,6-dichloro-*N*-(4-hydroxyphenyl)-1,4-benzoquinone monoimine dihydrate.

Dark-green powder, freely soluble in water and in anhydrous ethanol. The aqueous solution is dark blue; when acidified it becomes pink.

Dichlorophenolindophenol standard solution. *1027301.*

Dissolve 50.0 mg of *dichlorophenolindophenol, sodium salt R* in 100.0 mL of *water R* and filter.

Assay. Dissolve 20.0 mg of *ascorbic acid R* in 10 mL of a freshly prepared 200 g/L solution of *metaphosphoric acid R* and dilute to 250.0 mL with *water R*. Titrate 5.0 mL rapidly with the dichloro-phenolindophenol standard solution, added from a microburette graduated in 0.01 mL, until the pink colour persists for 10 s, the titration occupying not more than 2 min. Dilute the dichlorophenolindophenol solution with *water R* to make 1 mL of the solution equivalent to 0.1 mg of ascorbic acid ($C_6H_8O_6$).

Storage: use within 3 days.

Standardise immediately before use.

5,7-Dichloroquinolin-8-ol. $C_9H_5Cl_2NO$. (M_r 214.1). *1157000.* [773-76-2]. 5,7-Dichlorooxine.

Yellow, crystalline powder, soluble in acetone, slightly soluble in ethanol (96 per cent).

mp: about 179 °C.

Content: minimum 95.0 per cent.

Dichloroquinonechlorimide. $C_6H_2Cl_3NO$. (M_r 210.4). *1027400.* [101-38-2]. 2,6-Dichloro-*N*-chloro-1,4-benzoquinone mono-imine.

Pale yellow or greenish-yellow crystalline powder, practically insoluble in water, soluble in ethanol (96 per cent) and in dilute alkaline solutions.

mp: about 66 °C.

Dichlorvos. $C_4H_7Cl_2O_4P$. (M_r 221). *1101200.* [62-73-7]. 2,2-Dichlorovinyl dimethyl phosphate.

Colourless or brownish-yellow liquid, soluble in water, miscible with most organic solvents.

n_D^{25}: about 1.452.

Dicyclohexyl. $C_{12}H_{22}$. (M_r 166.3). *1135300.* [92-51-3]. Bicyclohexyl.

d_{20}^{20}: about 0.864.

bp: about 227 °C.

mp: about 4 °C.

Dicyclohexylamine. $C_{12}H_{23}N$. (M_r 181.3). *1027500.* [101-83-7]. *N,N*-Dicyclohexylamine.

Colourless liquid, sparingly soluble in water, miscible with the usual organic solvents.

n_D^{20}: about 1.484.

bp: about 256 °C.

Freezing point (*2.2.18*): 0 °C to 1 °C.

Dicyclohexylurea. $C_{13}H_{24}N_2O$. (M_r 224.4). *1027600.* [2387-23-7]. 1,3-Dicyclohexylurea.

White or almost white, crystalline powder.

mp: about 232 °C.

Didocosahexaenoin. $C_{47}H_{68}O_5$. (M_r 713.0). *1142700.* [88315-12-2]. Diglyceride of docosahexaenoic acid (C22:6). Glycerol didocosahexaenoate. (*all-Z*)-Docosahexaenoic acid, diester with propane-1,2,3-triol.

Didodecyl 3,3′-thiodipropionate. $C_{30}H_{58}O_4S$. (M_r 514.8). *1027700.* [123-28-4].

White or almost white, crystalline powder, practically insoluble in water, freely soluble in acetone and in light petroleum, slightly soluble in ethanol (96 per cent).

mp: about 39 °C.

Dieldrin. $C_{12}H_8Cl_6O$. (M_r 380.9). *1126200.* [60-57-1].

bp: about 385 °C.

mp: about 176 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Diethanolamine. $C_4H_{11}NO_2$. (M_r 105.1). *1027800.* [111-42-2]. 2,2′-Iminobisethanol.

Viscous, clear, slightly yellow liquid or deliquescent crystals melting at about 28 °C, very soluble in water, in acetone and in methanol.

d_{20}^{20}: about 1.09.

pH (*2.2.3*): 10.0 to 11.5 for a 50 g/L solution.

Diethanolamine used in the test for alkaline phosphatase complies with the following additional test.

Ethanolamine. Gas chromatography (*2.2.28*).

Internal standard solution. Dissolve 1.00 g of *3-aminopropanol R* in *acetone R* and dilute to 10.0 mL with the same solvent.

Test solution (a). Dissolve 5.00 g of the substance to be examined in *acetone R* and dilute to 10.0 mL with the same solvent.

Test solution (b). Dissolve 5.00 g of the substance to be examined in *acetone R*, add 1.0 mL of the internal standard solution and dilute to 10.0 mL with the same solvent.

Reference solutions. Dissolve 0.50 g of *ethanolamine R* in *acetone R* and dilute to 10.0 mL with the same solvent. To 0.5 mL, 1.0 mL and 2.0 mL of this solution, add 1.0 mL of the internal standard solution and dilute to 10.0 mL with *acetone R*.

Column:

– *size*: *l* = 1 m, Ø = 4 mm;
– *stationary phase*: *diphenylphenylene oxide polymer R* (180-250 µm).

Carrier gas: *nitrogen for chromatography R*.

Flow rate: 40 mL/min.

Temperature:

	Time (min)	Temperature (°C)
Column	0 → 3	125
	3 → 17.6	125 → 300
Injection port		250
Detector		280

Detection: flame-ionisation.

Injection: 1.0 µL.

Limit:

– *ethanolamine*: maximum 1.0 per cent.

Diethoxytetrahydrofuran. $C_8H_{16}O_3$. (M_r 160.2). *1027900.* [3320-90-9]. 2,5-Diethoxytetrahydrofuran. A mixture of the *cis* and *trans* isomers.

Clear, colourless or slightly yellowish liquid, practically insoluble in water, soluble in ethanol (96 per cent) and in most other organic solvents.

d_{20}^{20}: about 0.98.

n_D^{20}: about 1.418.

Diethylamine. $C_4H_{11}N$. (M_r 73.1). *1028000.* [109-89-7].

Clear, colourless, flammable liquid, strongly alkaline, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: about 0.71.

bp: about 55 °C.

Diethylaminoethyldextran. *1028200.*

Anion exchange resin presented as the hydrochloride.

Powder forming gels with water.

***N,N*-Diethylaniline.** $C_{10}H_{15}N$. (M_r 149.2). *1028400.* [91-66-7].

d_{20}^{20}: about 0.938.

bp: about 217 °C.

mp: about –38 °C.

Diethylene glycol. $C_4H_{10}O_3$. (M_r 106.1). *1028300.* [111-46-6]. 2,2′-Oxydiethanol.

Content: minimum 99.5 per cent *m/m*.

Clear, colourless liquid, hygroscopic, miscible with water, with acetone and with ethanol (96 per cent).

d_{20}^{20}: about 1.118.

n_D^{20}: about 1.447.

bp: 244 °C to 246 °C.

Storage: in an airtight container.

***N,N*-Diethylethane-1,2-diamine.** *1028500.* [100-36-7].

See *N,N-diethylethylenediamine R*.

***N,N*-Diethylethylenediamine.** $C_6H_{16}N_2$. (M_r 116.2). *1028500.* [100-36-7].

Content: minimum 98.0 per cent.

Slightly oily liquid, colourless or slightly yellow, strong odour of ammonia, irritant to the skin, eyes and mucous membranes.

d_{20}^{20}: 0.827.

bp: 145 °C to 147 °C.

Water (*2.5.12*): maximum 1.0 per cent, determined on 0.500 g.

Di(2-ethylhexyl) phthalate. $C_{24}H_{38}O_4$. (M_r 390.5). *1028100.* Di(2-ethylhexyl) benzene-1,2-dicarboxylate.

Colourless, oily liquid, practically insoluble in water, soluble in organic solvents.

d_{20}^{20}: about 0.98.

n_D^{20}: about 1.486.

Viscosity (*2.2.9*): about 80 mPa·s.

Diethylphenylenediamine sulfate. $C_{10}H_{18}N_2O_4S$. (M_r 262.3). *1028600.* [6283-63-2]. *N,N'*-Diethyl-*p*-phenylenediamine sulfate. *N,N'*-Diethylbenzene-1,4-diamine sulfate.

White or slightly yellow powder, soluble in water.

mp: about 185 °C, with decomposition.

Storage: protected from light.

Diethylphenylenediamine sulfate solution. *1028601.*

To 250 mL of *water R* add 2 mL of *sulfuric acid R* and 25 mL of *0.02 M sodium edetate*. Dissolve in this solution 1.1 g of *diethylphenylenediamine sulfate R* and dilute to 1000 mL with *water R*.

Do not use if the solution is not colourless.

Storage: protected from light and heat for 1 month.

Digitonin. $C_{56}H_{92}O_{29}$. (M_r 1229). *1028700.* [11024-24-1]. 3β-[*O*-β-D-Glucopyranosyl-(1→3)-*O*-β-D-galactopyranosyl-(1→2)-*O*-[β-D-xylopyranosyl-(1→3)]-*O*-β-D-galactopyranosyl-(1→4)-*O*-β-D-galactopyranosyloxy]-(25*R*)-5α-spirostan-2α,15β-diol.

Crystals, practically insoluble in water, sparingly soluble in anhydrous ethanol, slightly soluble in ethanol (96 per cent).

Digitoxin. *1028800.* [71-63-6].

See *Digitoxin (0078)*.

Dihydrocapsaicin. $C_{18}H_{29}NO_3$. (M_r 307.4). *1148100.* [19408-84-5]. *N*-[(4-Hydroxy-3-methoxyphenyl)methyl]-8-methylnonanamide.

White or almost white, crystalline powder, practically insoluble in cold water, freely soluble in anhydrous ethanol.

10,11-Dihydrocarbamazepine. $C_{15}H_{14}N_2O$. (M_r 238.3). *1028900.* [3564-73-6]. 10,11-Dihydro-5*H*-dibenzo[*b,f*]azepine-5-carboxamide.

mp: 205 °C to 210 °C.

Dihydrocarvone. $C_{10}H_{16}O$. (M_r 152.2). *1160900.* [7764-50-3]. *p*-Menth-8-en-2-one. 2-Methyl-5-(1-methylethenyl)cyclohexanone.

Dihydrocarvone used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the test for chromatographic profile in the monograph *Caraway oil (1817)*.

Content calculated by the normalisation procedure:

– *major component (trans-dihydrocarvone)*: minimum 70 per cent;

– *sum of cis- and trans-dihydrocarvone*: minimum 98 per cent.

2,5-Dihydroxybenzoic acid. $C_7H_6O_4$. (M_r 154.1). *1148200.* [490-79-9]. Gentisic acid.

Light yellow crystals.

mp: about 200 °C.

5,7-Dihydroxy-4-methylcoumarin. $C_{10}H_8O_4$. (M_r 192.2). *1149400.* [2107-76-8]. 5,7-Dihydroxy-4-methyl-2*H*-1-benzopyran-2-one.

Light yellowish powder, practically insoluble in water, sparingly soluble in ethanol (96 per cent).

mp: 295 °C to 303 °C.

Dihydroxynaphthalene. *1029000.* [132-86-5].

See *1,3-dihydroxynaphthalene R*.

1,3-Dihydroxynaphthalene. $C_{10}H_8O_2$. (M_r 160.2). *1029000.* [132-86-5]. Naphthalene-1,3-diol.

Crystalline, generally brownish-violet powder, freely soluble in water and in ethanol (96 per cent).

mp: about 125 °C.

2,7-Dihydroxynaphthalene. $C_{10}H_8O_2$. (M_r 160.2). *1029100.* [582-17-2]. Naphthalene-2,7-diol.

Needles, soluble in water and in ethanol (96 per cent).

mp: about 190 °C.

2,7-Dihydroxynaphthalene solution. *1029101.*

Dissolve 10 mg of *2,7-dihydroxynaphthalene R* in 100 mL of *sulfuric acid R* and allow to stand until decolorised.

Storage: use within 2 days.

5,7-Diiodoquinolin-8-ol. $C_9H_5I_2NO$. (M_r 397.0). *1157100.* [83-73-8]. 5,7-Diiodooxine.

Yellowish-brown powder, sparingly soluble in acetone and in ethanol (96 per cent).

Content: minimum 95.0 per cent.

Di-isobutyl ketone. $C_9H_{18}O$. (M_r 142.2). *1029200.* [108-83-8].

Clear, colourless liquid, slightly soluble in water, miscible with most organic solvents.

n_D^{20}: about 1.414

bp: about 168 °C.

Di-isopropyl ether. $C_6H_{14}O$. (M_r 102.2). *1029300.* [108-20-3].

Clear, colourless liquid, very slightly soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: 0.723 to 0.728.

bp: 67 °C to 69 °C.

Do not distil if the di-isopropyl ether does not comply with the test for peroxides.

Peroxides. Place 8 mL of *potassium iodide and starch solution R* in a 12 mL ground-glass-stoppered cylinder about 1.5 cm in diameter. Fill completely with the substance to be examined, shake vigorously and allow to stand protected from light for 30 min. No colour is produced.

The name and concentration of any added stabiliser are stated on the label.

Storage: protected from light.

***N,N'*-Diisopropylethylenediamine.** $C_8H_{20}N_2$. (M_r 144.3). *1140600.* [4013-94-9]. *N,N'*-bis(1-Methylethyl)-1,2-ethanediamine.

Colourless or yellowish, corrosive, flammable, hygroscopic liquid.

d_{20}^{20}: about 0.798.

n_D^{20}: about 1.429.

bp: about 170 °C.

4,4'-Dimethoxybenzophenone. $C_{15}H_{14}O_3$. (M_r 242.3). *1126300.* [90-96-0]. bis(4-Methoxyphenyl)methanone.

White or almost white powder, practically insoluble in water and slightly soluble in ethanol (96 per cent).

mp: about 142 °C.

Dimethoxypropane. $C_5H_{12}O_2$. (M_r 104.1). *1105200.* [77-76-9]. 2,2-Dimethoxypropane.

Colourless liquid, decomposing on exposure to moist air or water.

d_{20}^{20}: about 0.847.

n_D^{20}: about 1.378.

bp: about 83 °C.

Dimethylacetamide. C_4H_9NO. (M_r 87.1). *1029700.* [127-19-5]. *N,N*-Dimethylacetamide.

Content: minimum 99.5 per cent.

Colourless liquid, miscible with water and with many organic solvents.

d_{20}^{20}: about 0.94.

n_D^{20}: about 1.437.

bp: about 165 °C.

Dimethylamine. C_2H_7N. (M_r 45.08). *1168900.* [124-40-3]. *N*-methylmethanamine.

Colourless, flammable gas.

bp: about 7 °C.

mp: about – 92.2 °C.

Dimethylamine solution. *1168901.*

A 400 g/L solution.

Clear, colourless solution.

Density: about 0.89.

bp: about 54 °C.

mp: about – 37 °C.

Dimethylaminobenzaldehyde. $C_9H_{11}NO$. (M_r 149.2). *1029800.* [100-10-7]. 4-Dimethylaminobenzaldehyde.

White or yellowish-white crystals, soluble in ethanol (96 per cent) and in dilute acids.

mp: about 74 °C.

Dimethylaminobenzaldehyde solution R1. *1029801.*

Dissolve 0.2 g of *dimethylaminobenzaldehyde R* in 20 mL of *ethanol (96 per cent) R* and add 0.5 mL of *hydrochloric acid R*. Shake the solution with *activated charcoal R* and filter. The colour of the reagent is less intense than that of *iodine solution R3*. Prepare immediately before use.

Dimethylaminobenzaldehyde solution R2. *1029802.*

Dissolve 0.2 g of *dimethylaminobenzaldehyde R*, without heating, in a mixture of 4.5 mL of *water R* and 5.5 mL of *hydrochloric acid R*. Prepare immediately before use.

Dimethylaminobenzaldehyde solution R6. *1029803.*

Dissolve 0.125 g of *dimethylaminobenzaldehyde R* in a cooled mixture of 35 mL of *water R* and 65 mL of *sulfuric acid R*. Add 0.1 mL of a 50 g/L solution of *ferric chloride R*. Before use allow to stand for 24 h, protected from light.

Storage: when stored at room temperature, use within 1 week; when stored in a refrigerator use within several months.

Dimethylaminobenzaldehyde solution R7. *1029804.*

Dissolve 1.0 g of *dimethylaminobenzaldehyde R* in 50 mL of *hydrochloric acid R* and add 50 mL of *ethanol (96 per cent) R*.

Storage: protected from light; use within 4 weeks.

Dimethylaminobenzaldehyde solution R8. *1029805.*

Dissolve 0.25 g of *dimethylaminobenzaldehyde R* in a mixture of 5 g of *phosphoric acid R*, 45 g of *water R* and 50 g of *anhydrous acetic acid R*. Prepare immediately before use.

4-Dimethylaminocinnamaldehyde. $C_{11}H_{13}NO$. (M_r 175.2). *1029900.* [6203-18-5]. 3-(4-Dimethylaminophenyl)prop-2-enal.

Orange or orange-brown crystals or powder. Sensitive to light.

mp: about 138 °C.

4-Dimethylaminocinnamaldehyde solution. *1029901.*

Dissolve 2 g of *4-dimethylaminocinnamaldehyde R* in a mixture of 100 mL of *hydrochloric acid R1* and 100 mL of *anhydrous ethanol R*. Dilute the solution to four times its volume with *anhydrous ethanol R* immediately before use.

2-(Dimethylamino)ethyl methacrylate. $C_8H_{15}NO_2$. (M_r 157.2). *1147200.* [2867-47-2]. 2-(Dimethylamino)ethyl 2-methylpropenoate.

d_4^{20}: about 0.930.

bp: about 187 °C.

Dimethylaminonaphthalenesulfonyl chloride. $C_{12}H_{12}ClNO_2S$. (M_r 269.8). *1030000.* [605-65-2]. 5-Dimethyl-amino-1-naphthalenesulfonyl chloride.

Yellow, crystalline powder, slightly soluble in water, soluble in methanol.

mp: about 70 °C.

3-Dimethylaminophenol. $C_8H_{11}NO$. (M_r 137.2). *1156500.* [99-07-0]. 3-(Dimethylamino)phenol.

Grey powder, slightly soluble in water.

mp: about 80 °C.

Dimethylaniline. $C_8H_{11}N$. (M_r 121.2). *1030100.* [121-69-7]. *N,N*-Dimethylaniline.

Clear, oily liquid, almost colourless when freshly distilled, darkening on storage to reddish-brown, practically insoluble in water, freely soluble in ethanol (96 per cent).

n_D^{20}: about 1.558.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 192 °C and 194 °C.

***N,N*-Dimethylaniline.** *1030100.* [121-69-7].

See *Dimethylaniline R*.

2,3-Dimethylaniline. $C_8H_{11}N$. (M_r 121.2). *1105300.* [87-59-2]. 2,3-Xylidine.

Yellowish liquid, sparingly soluble in water, soluble in ethanol (96 per cent).

d_{20}^{20}: 0.993 to 0.995.

n_D^{20}: about 1.569.

bp: about 224 °C.

2,6-Dimethylaniline. $C_8H_{11}N$. (M_r 121.2). *1030200.* [87-62-7]. 2,6-Xylidine.

Colourless liquid, sparingly soluble in water, soluble in ethanol (96 per cent).

d_{20}^{20}: about 0.98.

2,6-Dimethylaniline hydrochloride. $C_8H_{12}ClN$. (M_r 157.6). *1169000.* [21436-98-6]. 2,6-Dimethylbenzenamide hydrochloride. 2,6-Xylidine hydrochloride.

Content: minimum 98.0 per cent.

2,4-Dimethyl-6-*tert*-butylphenol. $C_{12}H_{18}O$. (M_r 178.3). *1126500.* [1879-09-0].

Dimethyl carbonate. $C_3H_6O_3$. (M_r 90.1). *1119300.* [616-38-6]. Carbonic acid dimethyl ester.

Liquid, insoluble in water, miscible with ethanol (96 per cent).

d_4^{17}: 1.065.

n_D^{20}: 1.368.

bp: about 90 °C.

Dimethyl-β-cyclodextrin. $C_{56}H_{98}O_{35}$. (M_r 1331). *1169100.* [51166-71-3]. Heptakis(2,6-di-*O*-methyl)cyclomaltoheptaose. Cycloheptakis-(1→4)-(2,6-di-*O*-methyl-α-D-glucopyranosyl). $2^A,2^B,2^C,2^D,2^E,2^F,2^G,6^A,6^B,6^C,6^D,6^E,6^F,6^G$-Tetradeca-*O*-methyl-β-cyclodextrin.

White or almost white powder.

Dimethyldecylamine. $C_{12}H_{27}N$. (M_r 185.4). *1113500.* [1120-24-7]. *N,N*-dimethyldecylamine.

Content: minimum 98.0 per cent *m/m*.

bp: about 234 °C.

1,1-Dimethylethylamine. $C_4H_{11}N$. (M_r 73.1). *1100900.* [75-64-9]. 2-Amino-2-methylpropane. *tert*-Butylamine.

Liquid, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.694.

n_D^{20}: about 1.378.

bp: about 46 °C.

1,1-Dimethylethyl methyl ether. $C_5H_{12}O$. (M_r 88.1). *1013900.* [1634-04-4]. 2-Methoxy-2-methylpropane. *tert*-Butyl methyl ether.

Colourless, clear, flammable liquid.

n_D^{20}: about 1.376.

Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 50 per cent at 240 nm, 80 per cent at 255 nm, 98 per cent at 280 nm.

1,1-Dimethylethyl methyl ether R1. $C_5H_{12}O$. (M_r 88.1). *1126400.* [1634-04-4]. 2-Methoxy-2-methylpropane. *tert*-Butyl methyl ether.

Content: minimum 99.5 per cent.

d_{20}^{20}: about 0.741.

n_D^{20}: about 1.369.

bp: about 55 °C.

Dimethylformamide. C_3H_7NO. (M_r 73.1). *1030300.* [68-12-2].

Clear, colourless neutral liquid, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: 0.949 to 0.952.

bp: about 153 °C.

Water (*2.5.12*): maximum 0.1 per cent.

Dimethylformamide diethylacetal. $C_7H_{17}NO_2$. (M_r 147.2). *1113600.* [1188-33-6]. *N,N*-Dimethylformamide diethylacetal.

n_D^{20}: about 1.40.

bp: 128 °C to 130 °C.

***N,N*-Dimethylformamide dimethylacetal.** $C_5H_{13}NO_2$. (M_r 119.2). *1140700.* [4637-24-5]. 1,1-Dimethoxytrimethylamine.

Clear, colourless liquid.

d_{20}^{20}: about 0.896.

n_D^{20}: about 1.396.

bp: about 103 °C.

Dimethylglyoxime. $C_4H_8N_2O_2$. (M_r 116.1). *1030400.* [95-45-4]. 2,3-Butanedione dioxime.

White or almost white, crystalline powder or colourless crystals, practically insoluble in cold water, very slightly soluble in boiling water, soluble in ethanol (96 per cent).

mp: about 240 °C, with decomposition.

Sulfated ash (*2.4.14*): maximum 0.05 per cent.

1,3-Dimethyl-2-imidazolidinone. $C_5H_{10}N_2O$. (M_r 114.2). *1135400.* [80-73-9]. *N,N'*-Dimethylethylene urea. 1,3-Dimethyl-2-imidazolidone.

n_D^{20}: 1.4720.

bp: about 224 °C.

***N,N*-Dimethyloctylamine.** $C_{10}H_{23}N$. (M_r 157.3). *1030500.* [7378-99-6]. Octyldimethylamine.

Colourless liquid.

d_{20}^{20}: about 0.765.

n_D^{20}: about 1.424.

bp: about 195 °C.

2,5-Dimethylphenol. $C_8H_{10}O$. (M_r 122.2). *1162300.* [95-87-4]. *p*-Xylenol.

White or almost white crystals.

2,6-Dimethylphenol. $C_8H_{10}O$. (M_r 122.2). *1030600.* [576-26-1].

Colourless needles, slightly soluble in water, very soluble in ethanol (96 per cent).

bp: about 203 °C.

mp: 46 °C to 48 °C.

3,4-Dimethylphenol. $C_8H_{10}O$. (M_r 122.2). *1098100.* [95-65-8].

White or almost white crystals, slightly soluble in water, freely soluble in ethanol (96 per cent).

bp: about 226 °C.

mp: 25 °C to 27 °C.

***N,N*-Dimethyl-L-phenylalanine.** $C_{11}H_{15}NO_2$. (M_r 193.2). *1164000.* [17469-89-5]. (2*S*)-2-(Dimethylamino)-3-phenylpropanoic acid.

mp: about 226 °C.

Dimethylpiperazine. $C_6H_{14}N_2$. (M_r 114.2). *1030700.* [106-58-1]. 1,4-Dimethylpiperazine.

A colourless liquid, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: about 0.85.

n_D^{20}: about 1.446.

bp: about 131 °C.

Dimethylstearamide. $C_{20}H_{41}NO$. (M_r 311.6). *1030800.* *N,N*-Dimethylstearamide.

White or almost white solid mass, soluble in many organic solvents, including acetone.

mp: about 51 °C.

Dimethylstearylamide. *1030800.*

See *dimethylstearamide R*.

Dimethyl sulfone. $C_2H_6O_2S$. (M_r 94.1). *1030900.* [67-71-0].

White or almost white, crystalline powder, freely soluble in water, soluble in acetone and ethanol (96 per cent).

mp: 108 °C to 110 °C.

Dimethyl sulfoxide. *1029500.* [67-68-5].

See *Dimethyl sulfoxide (0763)*.

Dimethyl sulfoxide used in spectrophotometry complies with the following additional test.

Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 10 per cent at 262 nm, 35 per cent at 270 nm, 70 per cent at 290 nm, 98 per cent at 340 nm and at higher wavelengths.

Dimethyl sulfoxide R1. *1029501.*

Content: minimum 99.7 per cent, determined by gas chromatography.

Dimeticone. *1105400.* [9016-00-6].

See *Dimeticone (0138)*.

Dimidium bromide. $C_{20}H_{18}BrN_3$. (M_r 380.3). *1031100.* [518-67-2]. 3,8-Diamino-5-methyl-6-phenylphenanthridinium bromide.

Dark-red crystals, slightly soluble in water at 20 °C, sparingly soluble in water at 60 °C and in ethanol (96 per cent).

Dimidium bromide-sulfan blue mixed solution. *1031101.*

Dissolve separately 0.5 g of *dimidium bromide R* and 0.25 g of *sulfan blue R* in 30 mL of a hot mixture of 1 volume of *anhydrous ethanol R* and 9 volumes of *water R*, stir, mix the two solutions, and dilute to 250 mL with the same mixture of solvents. Mix 20 mL of this solution with 20 mL of a 14.0 per cent *V/V* solution of *sulfuric acid R* previously diluted with about 250 mL of *water R* and dilute to 500 mL with *water R*.

Storage: protected from light.

Dinitrobenzene. $C_6H_4N_2O_4$. (M_r 168.1). *1031200.* [528-29-0]. 1,3-Dinitrobenzene.

Yellowish crystalline powder or crystals, practically insoluble in water, slightly soluble in ethanol (96 per cent).

mp: about 90 °C.

Dinitrobenzene solution. *1031201.*

A 10 g/L solution in *ethanol (96 per cent) R*.

Dinitrobenzoic acid. $C_7H_4N_2O_6$. (M_r 212.1). *1031300.* [99-34-3]. 3,5-Dinitrobenzoic acid.

Almost colourless crystals, slightly soluble in water, very soluble in ethanol (96 per cent).

mp: about 206 °C.

Dinitrobenzoic acid solution. *1031301.*

A 20 g/L solution in *ethanol (96 per cent) R*.

Dinitrobenzoyl chloride. $C_7H_3ClN_2O_5$. (M_r 230.6). *1031400.* [99-33-2]. 3,5-Dinitrobenzoyl chloride.

Translucent, yellow or greenish-yellow powder or yellowish crystals, soluble in acetone and in toluene.

mp: about 68 °C.

Suitability test. To 1 mL of *anhydrous ethanol R* and 0.1 g of *dinitrobenzoyl chloride R* add 0.05 mL of *dilute sulfuric acid R* and boil under a reflux condenser for 30 min. After evaporation on a water-bath add 5 mL of *heptane R* to the residue and heat to boiling. Filter the hot solution. Wash the crystals formed on cooling to room temperature with a small quantity of *heptane R* and dry in a desiccator. The crystals melt (*2.2.14*) at 94 °C to 95 °C.

Dinitrophenylhydrazine. $C_6H_6N_4O_4$. (M_r 198.1). *1031500.* [119-26-6]. 2,4-Dinitrophenylhydrazine.

Reddish-orange crystals, very slightly soluble in water, slightly soluble in ethanol (96 per cent).

mp: about 203 °C (instantaneous method).

Dinitrophenylhydrazine-aceto-hydrochloric solution. *1031501.*

Dissolve 0.2 g of *dinitrophenylhydrazine R* in 20 mL of *methanol R* and add 80 mL of a mixture of equal volumes of *acetic acid R* and *hydrochloric acid R1*. Prepare immediately before use.

Dinitrophenylhydrazine-hydrochloric solution. *1031502.*

Dissolve by heating 0.50 g of *dinitrophenylhydrazine R* in *dilute hydrochloric acid R* and complete to 100 mL with the same solvent. Allow to cool and filter. Prepare immediately before use.

Dinitrophenylhydrazine-sulfuric acid solution. *1031503.*

Dissolve 1.5 g of *dinitrophenylhydrazine R* in 50 mL of a 20 per cent *V/V* solution of *sulfuric acid R*. Prepare immediately before use.

Dinonyl phthalate. $C_{26}H_{42}O_4$. (M_r 418.6). *1031600.* [28553-12-0].

Colourless to pale yellow, viscous liquid.

d_{20}^{20}: 0.97 to 0.98.

n_D^{20}: 1.482 to 1.489.

Acidity. Shake 5.0 g with 25 mL of *water R* for 1 min. Allow to stand, filter the separated aqueous layer and add 0.1 mL of *phenolphthalein solution R*. Not more than 0.3 mL of *0.1 M sodium hydroxide* is required to change the colour of the solution (0.05 per cent, calculated as phthalic acid).

Water (*2.5.12*): maximum 0.1 per cent.

Dioctadecyl disulfide. $C_{36}H_{74}S_2$. (M_r 571.1). *1031700.* [2500-88-1].

White or almost white powder, practically insoluble in water.

mp: 53 °C to 58 °C.

2,2′-Di(octadecyloxy)-5,5′-spirobi(1,3,2-dioxaphosphorinane). $C_{41}H_{82}O_6P_2$. (M_r 733). *1031800.*

White or almost white, waxy solid, practically insoluble in water, soluble in hydrocarbons.

mp: 40 °C to 70 °C.

Dioctadecyl 3,3′-thiodipropionate. $C_{42}H_{82}O_4S$. (M_r 683). *1031900.* [693-36-7].

White or almost white, crystalline powder, practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in acetone, in ethanol (96 per cent) and in light petroleum.

mp: 58 °C to 67 °C.

Dioxan. $C_4H_8O_2$. (M_r 88.1). *1032000.* [123-91-1]. 1,4-Dioxan.

Clear, colourless liquid, miscible with water and with most organic solvents.

d_{20}^{20}: about 1.03.

Freezing-point (*2.2.18*): 9 °C to 11 °C.

Water (*2.5.12*): maximum 0.5 per cent.

Do not distil if the dioxan does not comply with the test for peroxides.

Peroxides. Place 8 mL of *potassium iodide and starch solution R* in a 12 mL ground-glass-stoppered cylinder about 1.5 cm in diameter. Fill completely with the substance to be examined, shake vigorously and allow to stand in the dark for 30 min. No colour is produced.

Dioxan used for liquid scintillation is of a suitable analytical grade.

Dioxan solution. *1032002.*

Dilute 50.0 mL of *dioxan stock solution R* to 100.0 mL with *water R*. (0.5 mg/mL of dioxan).

Dioxan solution R1. *1032003.*

Dilute 10.0 mL of *dioxan solution R* to 50.0 mL with *water R*. (0.1 mg/mL of dioxan).

Dioxan stock solution. *1032001.*

Dissolve 1.00 g of *dioxan R* in *water R* and dilute to 100.0 mL with the same solvent. Dilute 5.0 mL of this solution to 50.0 mL with *water R* (1.0 mg/mL).

Diphenylamine. $C_{12}H_{11}N$. (M_r 169.2). *1032100.* [122-39-4].

White or almost white crystals, slightly soluble in water, soluble in ethanol (96 per cent).

mp: about 55 °C.

Storage: protected from light.

Diphenylamine solution. *1032101.*

A 1 g/L solution in *sulfuric acid R*.

Storage: protected from light.

Diphenylamine solution R1. *1032102.*

A 10 g/L solution in *sulfuric acid R*. The solution is colourless.

Diphenylamine solution R2. *1032103.*

Dissolve 1 g of *diphenylamine R* in 100 mL of *glacial acetic acid R* and add 2.75 mL of *sulfuric acid R*. Use immediately.

Diphenylanthracene. $C_{26}H_{18}$. (M_r 330.4). *1032200.* [1499-10-1]. 9,10-Diphenylanthracene.

Yellowish or yellow, crystalline powder, practically insoluble in water.

mp: about 248 °C.

Diphenylbenzidine. $C_{24}H_{20}N_2$. (M_r 336.4). *1032300.* [531-91-9]. *N,N′*-Diphenylbenzidine. *N,N′*-Diphenylbiphenyl-4,4′-diamine.

White or faintly grey, crystalline powder, practically insoluble in water, slightly soluble in acetone and in ethanol (96 per cent).

mp: about 248 °C.

Nitrates. Dissolve 8 mg in a cooled mixture of 5 mL of *water R* and 45 mL of *nitrogen-free sulfuric acid R*. The solution is colourless or very pale blue.

Sulfated ash (*2.4.14*): maximum 0.1 per cent.

Storage: protected from light.

Diphenylboric acid aminoethyl ester. $C_{14}H_{16}BNO$. (M_r 225.1). *1032400.* [524-95-8].

White or slightly yellow, crystalline powder, practically insoluble in water, soluble in ethanol (96 per cent).

mp: about 193 °C.

Diphenylcarbazide. $C_{13}H_{14}N_4O$. (M_r 242.3). *1032500.* [140-22-7]. 1,5-Diphenylcarbonodihydrazide.

White or almost white, crystalline powder which gradually becomes pink on exposure to air, very slightly soluble in water, soluble in acetone, in ethanol (96 per cent) and in glacial acetic acid.

mp: about 170 °C.

Sulfated ash (*2.4.14*): maximum 0.1 per cent.

Storage: protected from light.

Diphenylcarbazide solution. *1032501.*

Dissolve 0.2 g of *diphenylcarbazide R* in 10 mL of *glacial acetic acid R* and dilute to 100 mL with *anhydrous ethanol R*. Prepare immediately before use.

Diphenylcarbazone. $C_{13}H_{12}N_4O$. (M_r 240.3). *1032600.* [538-62-5]. 1,5-Diphenylcarbazone.

Orange-yellow, crystalline powder, practically insoluble in water, freely soluble in ethanol (96 per cent).

mp: about 157 °C, with decomposition.

Diphenylcarbazone mercuric reagent. *1032601.*

Solution A. Dissolve 0.1 g of *diphenylcarbazone R* in *anhydrous ethanol R* and dilute to 50 mL with the same solvent.

Solution B. Dissolve 1 g of *mercuric chloride R* in *anhydrous ethanol R* and dilute to 50 mL with the same solvent.

Mix equal volumes of the two solutions.

2,2-Diphenylglycine. $C_{14}H_{13}NO_2$. (M_r 227.26). *1174300.* [3060-50-2]. Amino(diphenyl)acetic acid.

1,2-Diphenylhydrazine. $C_{12}H_{12}N_2$. (M_r 184.3). *1140800.* [122-66-7]. Hydrazobenzene. 1,2-Diphenyldiazane.

Orange powder.

mp: about 125 °C.

Diphenylmethanol. $C_{13}H_{12}O$. (M_r 184.2). *1145700.* [91-01-0]. Benzhydrol.

White or almost white, crystalline powder.

mp: about 66 °C.

Diphenyloxazole. $C_{15}H_{11}NO$. (M_r 221.3). *1032700.* [92-71-7]. 2,5-Diphenyloxazole.

White or almost white powder, practically insoluble in water, soluble in methanol, sparingly soluble in dioxan and in glacial acetic acid.

mp: about 70 °C.

$A_{1\,cm}^{1\%}$: about 1260 determined at 305 nm in *methanol R*.

Diphenyloxazole used for liquid scintillation is of a suitable analytical grade.

Diphenylphenylene oxide polymer. *1032800.* 2,6-Diphenyl-*p*-phenylene oxide polymer.

White or almost white, porous beads. The size range of the beads is specified after the name of the reagent in the tests where it is used.

Diphosphorus pentoxide. P_2O_5. (M_r 141.9). *1032900.* [1314-56-3]. Phosphorus pentoxide. Phosphoric anhydride.

White or almost white powder, amorphous, deliquescent. It is hydrated by water with the evolution of heat.

Storage: in an airtight container.

Dipotassium hydrogen phosphate. K_2HPO_4. (M_r 174.2). *1033000.* [7758-11-4].

White or almost white, crystalline powder, hygroscopic, very soluble in water, slightly soluble in ethanol (96 per cent).

Storage: in an airtight container.

Dipotassium hydrogen phosphate trihydrate. $K_2HPO_4,3H_2O$. (M_r 228.2). *1157600.* [16788-57-1].

Colourless or white or almost white powder or crystals, freely soluble in water.

Dipotassium sulfate. K_2SO_4. (M_r 174.3). *1033100.* [7778-80-5].

Colourless crystals, soluble in water.

2,2′-Dipyridylamine. $C_{10}H_9N_3$. (M_r 171.2). *1157700.* [1202-34-2]. *N*-(Pyridin-2-yl)pyridin-2-amine.

mp: about 95 °C.

Disodium arsenate. $Na_2HAsO_4,7H_2O$. (M_r 312.0). *1102500.* [10048-95-0]. Disodium hydrogen arsenate heptahydrate. Dibasic sodium arsenate.

Crystals, efflorescent in warm air, freely soluble in water, soluble in glycerol, slightly soluble in ethanol (96 per cent). The aqueous solution is alcaline to litmus.

d_{20}^{20}: about 1.87.

mp: about 57 °C when rapidly heated.

Disodium bicinchoninate. $C_{20}H_{10}N_2Na_2O_4$. (M_r 388.3). *1126600.* [979-88-4]. Disodium 2,2′-biquinoline-4,4′-dicarboxylate.

Disodium hydrogen citrate. $C_6H_6Na_2O_7,1^1/_2H_2O$. (M_r 263.1). *1033200.* [144-33-2]. Sodium acid citrate. Disodium hydrogen 2-hydroxypropane-1,2,3-tricarboxylate sesquihydrate.

White or almost white powder, soluble in less than 2 parts of water, practically insoluble in ethanol (96 per cent).

Disodium hydrogen phosphate. *1033300.* [10039-32-4].

See *Disodium phosphate dodecahydrate (0118)*.

Disodium hydrogen phosphate solution. *1033301.*

A 90 g/L solution.

Disodium hydrogen phosphate, anhydrous. Na_2HPO_4. (M_r 142.0). *1033400.* [7558-79-4].

Disodium hydrogen phosphate dihydrate. *1033500.* [10028-24-7].

See *Disodium phosphate dihydrate (0602)*.

Disodium tetraborate. *1033600.* [1303-96-4].

See *Borax (0013)*.

Borate solution. *1033601.*

Dissolve 9.55 g of *disodium tetraborate R* in *sulfuric acid R*, heating on a water-bath, and dilute to 1 L with the same acid.

Ditalimphos. $C_{12}H_{14}NO_4PS$. (M_r 299.3). *1126700.* [5131-24-8]. *O,O*-Diethyl (1,3-dihydro-1,3-dioxo-2*H*-isoindol-2-yl)phosphonothioate.

Very slightly soluble in water, in ethyl acetate and in anhydrous ethanol.

A suitable certified reference solution may be used.

5,5′-Dithiobis(2-nitrobenzoic acid). $C_{14}H_8N_2O_8S_2$. (M_r 396.4). *1097300.* [69-78-3]. 3-Carboxy-4-nitrophenyldisulfide. Ellman's reagent. DTNB.

Yellow powder sparingly soluble in ethanol (96 per cent).

mp: about 242 °C.

Dithiol. $C_7H_8S_2$. (M_r 156.3). *1033800.* [496-74-2]. Toluene-3,4-dithiol. 4-Methylbenzene-1,2-dithiol.

White or almost white crystals, hygroscopic, soluble in methanol and in solutions of alkali hydroxides.

mp: about 30 °C.

Storage: in an airtight container.

Dithiol reagent. *1033801.*

To 1 g of *dithiol R* add 2 mL of *thioglycollic acid R* and dilute to 250 mL with a 20 g/L solution of *sodium hydroxide R*. Prepare immediately before use.

Dithiothreitol. $C_4H_{10}O_2S_2$. (M_r 154.2). *1098200.* [27565-41-9]. *threo*-1,4-Dimercaptobutane-2,3-diol.

Slightly hygroscopic needles, freely soluble in water, in acetone and in anhydrous ethanol.

Storage: in an airtight container.

Dithizone. $C_{13}H_{12}N_4S$. (M_r 256.3). *1033900.* [60-10-6]. 1,5-Diphenylthiocarbazone.

A bluish-black, brownish-black or black powder, practically insoluble in water, soluble in ethanol (96 per cent).

Storage: protected from light.

Dithizone solution. *1033901.*

A 0.5 g/L solution in *chloroform R*. Prepare immediately before use.

Dithizone solution R2. *1033903.*

Dissolve 40.0 mg of *dithizone R* in *chloroform R* and dilute to 1000.0 mL with the same solvent. Dilute 30.0 mL of the solution to 100.0 mL with *chloroform R*.

Assay. Dissolve a quantity of *mercuric chloride R* equivalent to 0.1354 g of $HgCl_2$ in a mixture of equal volumes of *dilute sulfuric acid R* and *water R* and dilute to 100.0 mL with the same mixture of solvents. Dilute 2.0 mL of this solution to 100.0 mL with a mixture of equal volumes of *dilute sulfuric acid R* and *water R*. (This solution contains 20 ppm of Hg). Transfer 1.0 mL of the solution to a separating funnel and add 50 mL of *dilute sulfuric acid R*, 140 mL of *water R* and 10 mL of a 200 g/L solution of *hydroxylamine hydrochloride R*. Titrate with the dithizone solution; after each addition, shake the mixture twenty times and towards the end of the titration allow to separate and discard the chloroform layer. Titrate until a bluish-green colour is obtained. Calculate the equivalent in micrograms of mercury per millilitre of the dithizone solution from the expression $20/V$, where V is the volume in millilitres of the dithizone solution used in the titration.

Dithizone R1. $C_{13}H_{12}N_4S$. (M_r 256.3). *1105500.* [60-10-6]. 1,5-Diphenylthiocarbazone.

Content: minimum 98.0 per cent.

Bluish-black, brownish-black or black powder, practically insoluble in water, soluble in ethanol (96 per cent).

Storage: protected from light.

Divanadium pentoxide. V_2O_5. (M_r 181.9). *1034000.* [1314-62-1]. Vanadic anhydride.

Content: minimum 98.5 per cent.

Yellow-brown or rust-brown powder, slightly soluble in water, soluble in strong mineral acids and in solutions of alkali hydroxides with formation of salts.

Appearance of solution. Heat 1 g for 30 min with 10 mL of *sulfuric acid R*. Allow to cool and dilute to 10 mL with the same acid. The solution is clear (*2.2.1*).

Sensitivity to hydrogen peroxide. Dilute 1.0 mL of the solution prepared for the test for appearance of solution cautiously to 50.0 mL with *water R*. To 0.5 mL of the solution add 0.1 mL of a solution of *hydrogen peroxide R* (0.1 g/L of H_2O_2). The solution has a distinct orange colour compared with a blank prepared from 0.5 mL of the solution to be examined and 0.1 mL of *water R*. After the addition of 0.4 mL of hydrogen peroxide solution (0.1 g/L H_2O_2), the orange solution becomes orange-yellow.

Loss on ignition: maximum 1.0 per cent, determined on 1.00 g at 700 ± 50 °C.

Assay. Dissolve 0.200 g with heating in 20 mL of a 70 per cent *m/m* solution of *sulfuric acid R*. Add 100 mL of *water R* and *0.02 M potassium permanganate* until a reddish colour is obtained. Decolorise the excess of potassium permanganate by the addition of a 30 g/L solution of *sodium nitrite R*. Add 5 g of *urea R* and 80 mL of a 70 per cent *m/m* solution of *sulfuric acid R*. Cool. Using 0.1 mL of *ferroin R* as indicator, titrate the solution immediately with *0.1 M ferrous sulfate* until a greenish-red colour is obtained.

1 mL of *0.1 M ferrous sulfate* is equivalent to 9.095 mg of V_2O_5.

Divanadium pentoxide solution in sulfuric acid. *1034001.*

Dissolve 0.2 g of *divanadium pentoxide R* in 4 mL of *sulfuric acid R* and dilute to 100 mL with *water R*.

Docosahexaenoic acid methyl ester. $C_{23}H_{34}O_2$. (M_r 342.5). *1142800.* [301-01-9]. DHA methyl ester. Cervonic acid methyl ester. (all-*Z*)-Docosa-4,7,10,13,16,19-hexaenoic acid methyl ester.

Content: minimum 90.0 per cent, determined by gas chromatography.

Docusate sodium. *1034100.* [577-11-7].

See *Docusate sodium (1418).*

Dodecyltrimethylammonium bromide. $C_{15}H_{34}BrN$. (M_r 308.4). *1135500.* [1119-94-4]. *N,N,N*-Trimethyldodecan-1-aminium bromide.

White or almost white crystals.

mp: about 246 °C.

D-Dopa. $C_9H_{11}NO_4$. (M_r 197.2). *1164100.* [5796-17-8]. (2*R*)-2-Amino-3-(3,4-dihydroxyphenyl)propanoic acid. 3-Hydroxy-D-tyrosine. 3,4-Dihydroxy-D-phenylalanine.

$[\alpha]_D^{20}$: + 9.5 to + 11.5, determined on a 10 g/L solution in *1 M hydrochloric acid*.

mp: about 277 °C.

Dotriacontane. $C_{32}H_{66}$. (M_r 450.9). *1034200.* [544-85-4]. *n*-Dotriacontane.

White or almost white plates, practically insoluble in water, sparingly soluble in hexane.

mp: about 69 °C.

Impurities. Not more than 0.1 per cent of impurities with the same t_R value as α-tocopherol acetate, determined by the gas chromatographic method prescribed in the monograph *α-Tocopherol acetate (0439).*

Doxycycline. *1145800.*

See *Doxycycline monohydrate (0820).*

Echinacoside. $C_{35}H_{46}O_{20}$. (M_r 786.5). *1159400.* [82854-37-3]. β-(3′,4′-Dihydroxyphenyl)-ethyl-*O*-α-L-rhamnopyranosyl (1→3)-*O*-β-D-[β-D-glucopyranosyl(1→6)]-(4-*O*-caffeoyl)-glucopyranoside.

Pale yellow powder, odourless.

Electrolyte reagent for the micro determination of water. *1113700.*

Commercially available anhydrous reagent or a combination of anhydrous reagents for the coulometric titration of water, containing suitable organic bases, sulfur dioxide and iodide dissolved in a suitable solvent.

Elementary standard solution for atomic spectrometry (1.000 g/L). *5004000.*

This solution is prepared, generally in acid conditions, from the element or a salt of the element whose minimum content is not less than 99.0 per cent. The quantity per litre of solution is greater than 0.995 g throughout the guaranteed period, as long as the vial has not been opened. The starting material (element or salt) and the characteristics of the final solvent (nature and acidity, etc.) are mentioned on the label.

Emetine dihydrochloride. *1034300.* [316-42-7].

See *Emetine hydrochloride pentahydrate (0081).*

Emodin. $C_{15}H_{10}O_5$. (M_r 270.2). *1034400.* [518-82-1].
1,3,8-Trihydroxy-6-methylanthraquinone.

Orange-red needles, practically insoluble in water, soluble in ethanol (96 per cent) and in solutions of alkali hydroxides.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Rhubarb (0291)*; the chromatogram shows only one principal spot.

Endoprotease LysC. *1173200.*

Microbial extracellular proteolytic enzyme secreted by *Achromobacter lyticus.* A lyophilised powder, free of salts.

α-Endosulfan. $C_9H_6Cl_6O_3S$. (M_r 406.9). *1126800.* [959-98-8].

bp: about 200 °C.

mp: about 108 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

β-Endosulfan. $C_9H_6Cl_6O_3S$. (M_r 406.9). *1126900.* [33213-65-9].

bp: about 390 °C.

mp: about 207 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Endrin. $C_{12}H_8Cl_6O$. (M_r 380.9). *1127000.* [72-20-8].

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Erucamide. $C_{22}H_{43}NO$. (M_r 337.6). *1034500.* [112-84-5].
(*Z*)-Docos-13-enoamide.

Yellowish or white powder or granules, practically insoluble in water, very soluble in methylene chloride, soluble in anhydrous ethanol.

mp: about 70 °C.

Erythritol. *1113800.* [149-32-6].

See *Erythritol (1803).*

Esculin. $C_{15}H_{16}O_9,1^1/_2H_2O$. ($M_r$ 367.3). *1119400.* [531-75-9].
6-(β-D-Glucopyranosyloxy)-7-hydroxy-2*H*-chromen-2-one.

White or almost white powder or colourless crystals, sparingly soluble in water and in ethanol (96 per cent), freely soluble in hot water and in hot ethanol (96 per cent).

Chromatography (*2.2.27*). Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Eleutherococcus (1419)*; the chromatogram shows only one principal spot.

Estradiol. $C_{18}H_{24}O_2$. (M_r 272.4). *1135600.* [50-28-2].
Estra-1,3,5(10)-triene-3,17β-diol. β-Estradiol.

Prisms stable in air, practically insoluble in water, freely soluble in ethanol (96 per cent), soluble in acetone and in dioxane, sparingly soluble in vegetable oils.

mp: 173 °C to 179 °C.

17α-Estradiol. $C_{18}H_{24}O_2$. (M_r 272.4). *1034600.* [57-91-0].

White or almost white, crystalline powder or colourless crystals.

mp: 220 °C to 223 °C.

Estragole. $C_{10}H_{12}O$. (M_r 148.2). *1034700.* [140-67-0].
1-Methoxy-4-prop-2-enylbenzene.

Liquid, miscible with ethanol (96 per cent).

n_D^{20}: about 1.52.

bp: about 216 °C.

Estragole used in gas chromatography complies with the following test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Anise oil (0804).*

Test solution. The substance to be examined.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Ethanol. *1034800.* [64-17-5].

See *Ethanol, anhydrous R.*

Ethanol, anhydrous. *1034800.* [64-17-5].

See *Ethanol, anhydrous (1318).*

Ethanol R1. *1034801.*

Complies with the requirements prescribed for the monograph *Ethanol, anhydrous (1318)* with the following additional requirement.

Methanol. Gas chromatography (*2.2.28*).

Test solution. The substance to be examined.

Reference solution. Dilute 0.50 mL of *anhydrous methanol R* to 100.0 mL with the substance to be examined. Dilute 1.0 mL of this solution to 100.0 mL with the substance to be examined.

Column:

– *material*: glass;
– *size*: *l* = 2 m, Ø = 2 mm;
– *stationary phase*: *ethylvinylbenzene-divinyl-benzene copolymer R* (75-100 µm).

Carrier gas: *nitrogen for chromatography R.*

Flow rate: 30 mL/min.

Temperature:

– *column*: 130 °C;
– *injection port*: 150 °C;
– *detector*: 200 °C.

Detection: flame-ionisation.

Injection: 1 µL of the test solution and 1 µL of the reference solution, alternately, three times.

After each chromatography, heat the column to 230 °C for 8 min. Integrate the methanol peak. Calculate the percentage methanol content from the following expression:

$$\frac{a \times b}{c - b}$$

a = percentage *V/V* content of methanol in the reference solution,
b = area of the methanol peak in the chromatogram obtained with the test solution,
c = area of the methanol peak in the chromatogram obtained with the reference solution.

Limit:

– *methanol*: maximum 0.005 per cent *V/V*.

Ethanol (96 per cent). *1002500.* [64-17-5].

See *Ethanol (96 per cent) (1317).*

Ethanol (*x* per cent *V/V*). *1002502.*

Mix appropriate volumes of *water R* and *ethanol (96 per cent) R*, allowing for the effects of warming and volume contraction inherent to the preparation of such a mixture, to obtain a solution whose final content of ethanol corresponds to the value of *x*.

Ethanolamine. C_2H_7NO. (M_r 61.1). *1034900.* [141-43-5].
2-Aminoethanol.

Clear, colourless, viscous, hygroscopic liquid, miscible with water and with methanol.

d_{20}^{20}: about 1.04.

n_D^{20}: about 1.454.

mp: about 11 °C.

Storage: in an airtight container.

Ether. $C_4H_{10}O$. (M_r 74.1). *1035000.* [60-29-7].

Clear, colourless, volatile and very mobile liquid, very flammable, hygroscopic, soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: 0.713 to 0.715.

bp: 34 °C to 35 °C.

Do not distil if the ether does not comply with the test for peroxides.

Peroxides. Place 8 mL of *potassium iodide and starch solution R* in a 12 mL ground-glass-stoppered cylinder about 1.5 cm in diameter. Fill completely with the substance to be examined, shake vigorously and allow to stand in the dark for 30 min. No colour is produced.

The name and concentration of any added stabilisers are stated on the label.

Storage: in an airtight container, protected from light, at a temperature not exceeding 15 °C.

Ether, peroxide-free. *1035100.*

See *Anaesthetic ether (0367).*

Ethion. $C_9H_{22}O_4P_2S_4$. (M_r 384.5). *1127100.* [563-12-2].

mp: – 24 °C to – 25 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Ethoxychrysoidine hydrochloride. $C_{14}H_{17}ClN_4O$. (M_r 292.8). *1035200.* [2313-87-3]. 4-[(4-Ethoxyphenyl)diazenyl]phenylene-1,3-diamine hydrochloride.

Reddish powder, soluble in ethanol (96 per cent).

Ethoxychrysoidine solution. *1035201.*

A 1 g/L solution in *ethanol (96 per cent) R*.

Test for sensitivity. To a mixture of 5 mL of *dilute hydrochloric acid R* and 0.05 mL of the ethoxy-chrysoidine solution add 0.05 mL of *0.0167 M bromide-bromate.* The colour changes from red to light yellow within 2 min.

Ethyl acetate. $C_4H_8O_2$. (M_r 88.1). *1035300.* [141-78-6].

Clear, colourless liquid, soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: 0.901 to 0.904.

bp: 76 °C to 78 °C.

Ethyl acetate, treated. *1035301.*

Disperse 200 g of *sulfamic acid R* in *ethyl acetate R* and make up to 1000 mL with the same solvent. Stir the suspension obtained for three days and filter through a filter paper.

Storage: use within 1 month.

Ethyl acrylate. $C_5H_8O_2$. (M_r 100.1). *1035400.* [140-88-5]. Ethyl prop-2-enoate.

Colourless liquid.

d_{20}^{20}: about 0.924.

n_D^{20}: about 1.406.

bp: about 99 °C.

mp: about – 71 °C.

4-[(Ethylamino)methyl]pyridine. $C_8H_{12}N_2$. (M_r 136.2). *1101300.* [33403-97-3].

Pale yellow liquid.

d_{20}^{20}: about 0.98.

n_D^{20}: about 1.516.

bp: about 98 °C.

Ethylbenzene. C_8H_{10}. (M_r 106.2). *1035800.* [100-41-4].

Content: minimum 99.5 per cent *m/m*, determined by gas chromatography.

Clear, colourless liquid, practically insoluble in water, soluble in acetone, and in ethanol (96 per cent).

d_{20}^{20}: about 0.87.

n_D^{20}: about 1.496.

bp: about 135 °C.

Ethyl benzoate. $C_9H_{10}O_2$. (M_r 150.2). *1135700.* [93-89-0].

A clear, colourless, refractive liquid, practically insoluble in water, miscible with ethanol (96 per cent) and with light petroleum.

d_4^{25}: about 1.050.

n_D^{20}: about 1.506.

bp: 211 °C to 213 °C.

Ethyl 5-bromovalerate. $C_7H_{13}BrO_2$. (M_r 209.1). *1142900.* [14660-52-7]. Ethyl 5-bromopentanoate.

Clear, colourless liquid.

d_{20}^{20}: about 1.321.

bp: 104 °C to 109 °C.

Ethyl cyanoacetate. $C_5H_7NO_2$. (M_r 113.1). *1035500.* [105-56-6].

Colourless or pale yellow liquid, slightly soluble in water, miscible with ethanol (96 per cent).

bp: 205 °C to 209 °C, with decomposition.

Ethylene chloride. $C_2H_4Cl_2$. (M_r 99.0). *1036000.* [107-06-2]. 1,2-Dichloroethane.

Clear, colourless liquid, soluble in about 120 parts of water and in 2 parts of ethanol (96 per cent).

d_{20}^{20}: about 1.25.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 82 °C and 84 °C.

Ethylenediamine. $C_2H_8N_2$. (M_r 60.1). *1036500.* [107-15-3]. Ethane-1,2-diamine.

Clear, colourless, fuming liquid, strongly alkaline, miscible with water and with ethanol (96 per cent).

bp: about 116 °C.

Ethylene bis[3,3-di(3-*tert*-butyl-4-hydroxyphenyl)butyrate]. *1035900.* [32509-66-3].

See *ethylene bis[3,3-di(3-(1,1-dimethylethyl)-4-hydroxyphenyl)butyrate] R*.

Ethylene bis[3,3-di(3-(1,1-dimethylethyl)-4-hydroxyphenyl)butyrate]. $C_{50}H_{66}O_8$. (M_r 795). *1035900.* [32509-66-3]. Ethylene bis[3,3-di(3-*tert*-butyl-4-hydroxyphenyl)butyrate].

Crystalline powder, practically insoluble in water and in light petroleum, very soluble in acetone and in methanol.

mp: about 165 °C.

(Ethylenedinitrilo)tetra-acetic acid. $C_{10}H_{16}N_2O_8$. (M_r 292.2). *1105800.* [60-00-4]. *N,N'*-1,2-Ethanediylbis[*N*-(carboxymethyl)glycine]. Edetic acid.

White or almost white crystalline powder, very slightly soluble in water.

mp: about 250 °C, with decomposition.

Ethylene glycol. $C_2H_6O_2$. (M_r 62.1). *1036100.* [107-21-1]. Ethane-1,2-diol.

Content: minimum 99.0 per cent.

Colourless, slightly viscous liquid, hygroscopic, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: 1.113 to 1.115.

n_D^{20}: about 1.432.

bp: about 198 °C.

mp: about – 12 °C.

Acidity. To 10 mL add 20 mL of *water R* and 1 mL of *phenolphthalein solution R*. Not more than 0.15 mL of *0.02 M sodium hydroxide* is required to change the colour of the indicator to pink.

Water (*2.5.12*): maximum 0.2 per cent

Ethylene glycol monoethyl ether. $C_4H_{10}O_2$. (M_r 90.1). *1036200.* [110-80-5]. 2-Ethoxyethanol.

Content: minimum 99.0 per cent.

Clear, colourless liquid, miscible with water, with acetone and with ethanol (96 per cent).

d_{20}^{20}: about 0.93.

n_D^{25}: about 1.406.

bp: about 135 °C.

Ethylene glycol monomethyl ether. $C_3H_8O_2$. (M_r 76.1). *1036300.* [109-86-4]. 2-Methoxyethanol.

Content: minimum 99.0 per cent.

Clear, colourless liquid, miscible with water, with acetone and with ethanol (96 per cent).

d_{20}^{20}: about 0.97.

n_D^{20}: about 1.403.

bp: about 125 °C.

Ethylene oxide. C_2H_4O. (M_r 44.05). *1036400.* [75-21-8]. Oxirane.

Colourless, flammable gas, very soluble in water and in anhydrous ethanol.

Liquefaction point: about 12 °C.

Ethylene oxide solution. *1036402.*

Weigh a quantity of cool *ethylene oxide stock solution R* equivalent to 2.5 mg of ethylene oxide into a cool flask and dilute to 50.0 g with *macrogol 200 R1*. Mix well and dilute 2.5 g of this solution to 25.0 mL with *macrogol 200 R1* (5 µg of ethylene oxide per gram of solution). *Prepare immediately before use.*

Ethylene oxide solution R1. *1036403.*

Dilute 1.0 mL of cooled *ethylene oxide stock solution R* (check the exact volume by weighing) to 50.0 mL with *macrogol 200 R1*. Mix well and dilute 2.5 g of this solution to 25.0 mL with *macrogol 200 R1*. Calculate the exact amount of ethylene oxide in parts per million from the volume determined by weighing and taking the relative density of *macrogol 200 R1* as 1.127. *Prepare immediately before use.*

Ethylene oxide solution R2. *1036404.*

Weigh 1.00 g of cold *ethylene oxide stock solution R* (equivalent to 2.5 mg of ethylene oxide) into a cold flask containing 40.0 g of cold *macrogol 200 R1*. Mix and determine the exact mass and dilute to a calculated mass to obtain a solution containing 50 µg of ethylene oxide per gram of solution. Weigh 10.00 g into a flask containing about 30 mL of *water R*, mix and dilute to 50.0 mL with *water R* (10 µg/mL of ethylene oxide). *Prepare immediately before use.*

Ethylene oxide solution R3. *1036405.*

Dilute 10.0 mL of *ethylene oxide solution R2* to 50.0 mL with *water R* (2 µg/mL of ethylene oxide). *Prepare immediately before use.*

Ethylene oxide solution R4. *1036407.*

Dilute 1.0 mL of *ethylene oxide stock solution R1* to 100.0 mL with *water R*. Dilute 1.0 mL of this solution to 25.0 mL with *water R*.

Ethylene oxide solution R5. *1036408.*

A 50 g/L solution of *ethylene oxide R* in *methylene chloride R*.

Either use a commercially available reagent or prepare the solution corresponding to the above-mentioned composition.

Ethylene oxide stock solution. *1036401.*

All operations carried out in the preparation of these solutions must be conducted in a fume-hood. The operator must protect both hands and face by wearing polyethylene protective gloves and an appropriate face mask.

Store all solutions in an airtight container in a refrigerator at 4 °C to 8 °C. Carry out all determinations three times.

Into a dry, clean test-tube, cooled in a mixture of 1 part of *sodium chloride R* and 3 parts of crushed ice, introduce a slow current of *ethylene oxide R* gas, allowing condensation onto the inner wall of the test-tube. Using a glass syringe, previously cooled to – 10 °C, inject about 300 µL (corresponding to about 0.25 g) of liquid *ethylene oxide R* into 50 mL of *macrogol 200 R1*. Determine the absorbed quantity of ethylene oxide by weighing before and after absorption (M_{eo}). Dilute to 100.0 mL with *macrogol 200 R1*. Mix well before use.

Assay. To 10 mL of a 500 g/L suspension of *magnesium chloride R* in *anhydrous ethanol R* add 20.0 mL of *0.1 M alcoholic hydrochloric acid* in a flask. Stopper and shake to obtain a saturated solution and allow to stand overnight to equilibrate. Weigh 5.00 g of *ethylene oxide stock solution (2.5 g/L) R* into the flask and allow to stand for 30 min. Titrate with *0.1 M alcoholic potassium hydroxide* determining the end-point potentiometrically (*2.2.20*).

Carry out a blank titration, replacing the substance to be examined with the same quantity of *macrogol 200 R1*.

Ethylene oxide content in milligrams per gram is given by:

$$\frac{(V_0 - V_1) \times f \times 4.404}{m}$$

V_0, V_1 = volumes of *0.1 M alcoholic potassium hydroxide* used respectively for the blank titration and the assay,

f = factor of the alcoholic potassium hydroxide solution,

m = mass of the sample taken (g).

Ethylene oxide stock solution R1. *1036406.*

A 50 g/L solution of *ethylene oxide R* in *methanol R*.

Ethyl formate. $C_3H_6O_2$. (M_r 74.1). *1035600.* [109-94-4]. Ethyl methanoate.

Clear, colourless, flammable liquid, freely soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.919.

n_D^{20}: about 1.36.

bp: about 54 °C.

2-Ethylhexane-1,3-diol. $C_8H_{18}O_2$. (M_r 146.2). *1105900.* [94-96-2].

Slightly oily liquid, soluble in anhydrous ethanol, 2-propanol, propylene glycol and castor oil.

d_{20}^{20}: about 0.942.

n_D^{20}: about 1.451.

bp: about 244 °C.

2-Ethylhexanoic acid. $C_8H_{16}O_2$. (M_r 144.2). *1036600.* [149-57-5].

Colourless liquid.

d_{20}^{20}: about 0.91.

n_D^{20}: about 1.425.

Related substances. Gas chromatography (*2.2.28*).

Injection: 1 µL of the test solution.

Test solution: suspend 0.2 g of the 2-ethylhexanoic acid in 5 mL of *water R*, add 3 mL of *dilute hydrochloric acid R* and 5 mL of *hexane R*, shake for 1 min, allow the layers to separate and use the upper layer. Carry out the chromatographic procedure as prescribed in the test for 2-ethylhexanoic acid in the monograph on *Amoxicillin sodium (0577)*.

Limit: the sum of the area of any peaks, apart from the principal peak and the peak due to the solvent, is not greater than 2.5 per cent of the area of the principal peak.

Ethyl 4-hydroxybenzoate. *1035700.* [120-47-8].

See *Ethyl parahydroxybenzoate R*.

_N_-Ethylmaleimide. $C_6H_7NO_2$. (M_r 125.1). *1036700.* [128-53-0]. 1-Ethyl-1*H*-pyrrole-2,5-dione.

Colourless crystals, sparingly soluble in water, freely soluble in ethanol (96 per cent).

mp: 41 °C to 45 °C.

Storage: at a temperature of 2 °C to 8 °C.

Ethyl methyl ketone. *1054100.* [78-93-3].

See *methyl ethyl ketone R*.

2-Ethyl-2-methylsuccinic acid. $C_7H_{12}O_4$. (M_r 160.2). *1036800.* [631-31-2]. 2-Ethyl-2-methylbutanedioic acid.

mp: 104 °C to 107 °C.

Ethyl parahydroxybenzoate. *1035700.* [120-47-8].

See *Ethyl parahydroxybenzoate (0900)*.

2-Ethylpyridine. C_7H_9N. (M_r 107.2). *1133400.* [100-71-0].

Colourless or brownish liquid.

d_{20}^{20}: about 0.939.

n_D^{20}: about 1.496.

bp: about 149 °C.

Ethylvinylbenzene-divinylbenzene copolymer. *1036900.*

Porous, rigid, cross-linked polymer beads. Several grades are available with different sizes of bead. The size range of the beads is specified after the name of the reagent in the tests where it is used.

Ethylvinylbenzene-divinylbenzene copolymer R1. *1036901.*

Porous, rigid, cross-linked polymer beads, with a nominal specific surface area of 500 m^2/g to 600 m^2/g and having pores with a mean diameter of 7.5 nm. Several grades are available with different sizes of beads. The size range of the beads is specified after the name of the reagent in the tests where it is used.

Eugenol. $C_{10}H_{12}O_2$. (M_r 164.2). *1037000.* [97-53-0]. 4-Allyl-2-methoxyphenol.

Colourless or pale yellow, oily liquid, darkening on exposure to air and light and becoming more viscous, practically insoluble in water, miscible with ethanol (96 per cent) and with fatty and essential oils.

d_{20}^{20}: about 1.07.

bp: about 250 °C.

Eugenol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Clove oil (1091)*.

Test solution. The substance to be examined.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Storage: protected from light.

Euglobulins, bovine. *1037100.*

Use fresh bovine blood collected into an anticoagulant solution (for example, sodium citrate solution). Discard any haemolysed blood. Centrifuge at 1500-1800 *g* at 15-20 °C to obtain a supernatant plasma poor in platelets.

To 1 L of bovine plasma add 75 g of *barium sulfate R* and shake for 30 min. Centrifuge at not less than 1500-1800 *g* at 15-20 °C and draw off the clear supernatant liquid. Add 10 mL of a 0.2 mg/mL solution of *aprotinin R* and shake to ensure mixing. In a container with a minimum capacity of 30 L in a chamber at 4 °C introduce 25 L of *distilled water R* at 4 °C and add about 500 g of solid carbon dioxide. Immediately add, while stirring, the supernatant liquid obtained from the plasma. A white precipitate is formed. Allow to settle at 4 °C for 10-15 h. Remove the clear supernatant solution by siphoning. Collect the precipitate by centrifuging at 4 °C. Suspend the precipitate by dispersing mechanically in 500 mL of *distilled water R* at 4 °C, shake for 5 min and collect the precipitate by centrifuging at 4 °C. Disperse the precipitate mechanically in 60 mL of a solution containing 9 g/L of *sodium chloride R* and 0.9 g/L *sodium citrate R* and adjust to pH 7.2-7.4 by adding a 10 g/L solution of *sodium hydroxide R*. Filter through a sintered glass filter (*2.1.2*); to facilitate the dissolution of the precipitate crush the particles of the precipitate with a suitable instrument. Wash the filter and the instrument with 40 mL of the chloride-citrate solution described above and dilute to 100 mL with the same solution. Freeze-dry the solution. The yields are generally 6 g to 8 g of euglobulins per litre of bovine plasma.

Test for suitability. For this test, prepare the solutions using *phosphate buffer solution pH 7.4 R* containing 30 g/L of *bovine albumin R*.

Into a test-tube 8 mm in diameter placed in a water-bath at 37 °C introduce 0.2 mL of a solution of a reference preparation of urokinase containing 100 IU/mL and 0.1 mL of a solution of *human thrombin R* containing 20 IU/mL. Add rapidly 0.5 mL of a solution containing 10 mg of bovine euglobulins per millilitre. A firm clot forms in less than 10 s. Note the time that elapses between the addition of the solution of bovine euglobulins and the lysis of the clot. The lysis time does not exceed 15 min.

Storage: protected from moisture at 4 °C; use within 1 year.

Euglobulins, human. *1037200.*

For the preparation, use fresh human blood collected into an anticoagulant solution (for example sodium citrate solution) or human blood for transfusion that has been collected in plastic blood bags and which has just reached its expiry date. Discard any haemolysed blood. Centrifuge at 1500-1800 *g* at 15 °C to obtain a supernatant plasma poor in platelets. Iso-group plasmas may be mixed.

To 1 L of the plasma add 75 g of *barium sulfate R* and shake for 30 min. Centrifuge at not less than 15 000 *g* at 15 °C and draw off the clear supernatant liquid. Add 10 mL of a solution of *aprotinin R* containing 0.2 mg/mL and shake to ensure mixing. In a container with a minimum capacity of 30 L in a chamber at 4 °C introduce 25 L of *distilled water R* at 4 °C and add about 500 g of solid carbon dioxide. Immediately add while stirring the supernatant liquid obtained from the plasma. A white precipitate is formed. Allow to settle at 4 °C for 10-15 h. Remove the clear supernatant solution by siphoning. Collect the precipitate by centrifuging at 4 °C. Suspend the precipitate by dispersing mechanically in 500 mL of *distilled water R* at 4 °C, shake for 5 min and collect the precipitate by centrifuging at 4 °C. Disperse the precipitate mechanically in 60 mL of a solution containing 9 g/L of *sodium chloride R* and 0.9 g/L of *sodium citrate R*, and adjust the pH to 7.2-7.4 by adding a 10 g/L solution of *sodium hydroxide R*. Filter through a sintered-glass filter (*2.1.2*); to facilitate the dissolution of the precipitate crush the particles of the precipitate with a suitable instrument. Wash the filter and the instrument with 40 mL of the chloride-citrate solution described above and dilute to 100 mL with the same solution. Freeze-dry the solution. The yields are generally 6 g to 8 g of euglobulins per litre of human plasma.

Test for suitability. For this test, prepare the solutions using *phosphate buffer solution pH 7.2 R* containing 30 g/L of *bovine albumin R*. Into a test-tube 8 mm in diameter placed in a water-bath at 37 °C introduce 0.1 mL of a solution of a reference preparation of streptokinase containing 10 IU of streptokinase activity per millilitre and 0.1 mL of a solution of *human thrombin R* containing 20 IU/mL. Add rapidly 1 mL of a solution containing 10 mg of human euglobulins per millilitre. A firm clot forms in less than 10 s. Note the time that elapses between the addition of the solution of human euglobulins and the lysis of the clot. The lysis time does not exceed 15 min.

Storage: in an airtight container at 4 °C; use within 1 year.

Factor Xa, bovine, coagulation. *1037300.* [9002-05-5].

An enzyme which converts prothrombin to thrombin. The semi-purified preparation is obtained from liquid bovine plasma and it may be prepared by activation of the zymogen factor X with a suitable activator such as Russell's viper venom.

Storage: freeze-dried preparation at – 20 °C and frozen solution at a temperature lower than – 20 °C.

Factor Xa solution, bovine. *1037301.*

Reconstitute as directed by the manufacturer and dilute with *tris(hydroxymethyl)aminomethane sodium chloride buffer solution pH 7.4 R*.

Any change in the absorbance of the solution, measured at 405 nm (*2.2.25*) against *tris(hydroxymethyl)aminomethane sodium chloride buffer solution pH 7.4 R* and from which the blank absorbance has been substracted, is not more than 0.20 per minute.

Factor Xa solution, bovine R1. *1037302.*

Reconstitute as directed by the manufacturer and dilute to 1.4 nkat/mL with *tris(hydroxymethyl)aminomethane EDTA buffer solution pH 8.4 R*.

***(E,E)*-Farnesol.** $C_{15}H_{26}O$. (M_r 222.4). *1161000.* [106-28-5]. *trans,trans*-Farnesol. (2*E*,6*E*)-3,7,11-Trimethyldodeca-2,6,10-trien-1-ol.

Fast blue B salt. $C_{14}H_{12}Cl_2N_4O_2$. (M_r 339.2). *1037400.* [84633-94-3].

Schultz No. 490.

Colour Index No. 37235.

3,3′-Dimethoxy(biphenyl)-4,4′-bisdiazonium dichloride.

Dark green powder, soluble in water. It is stabilised by addition of zinc chloride.

Storage: in an airtight container, at a temperature between 2 °C and 8 °C.

Fast red B salt. $C_{17}H_{13}N_3O_9S_2$. (M_r 467.4). *1037500.* [56315-29-8].

Schultz No. 155.

Colour Index No. 37125.

2-Methoxy-4-nitrobenzenediazonium hydrogen naphthalene-1,5-disulfonate.

Orange-yellow powder, soluble in water, slightly soluble in ethanol (96 per cent).

Storage: in an airtight container, protected from light, at 2 °C to 8 °C.

Fenchlorphos. $C_8H_8Cl_3O_3PS$. (M_r 321.5). *1127200.* [299-84-3].

mp: about 35 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Fenchone. $C_{10}H_{16}O$. (M_r 152.2). *1037600.* [7787-20-4]. (1*R*)-1,3,3-Trimethylbicyclo[2.2.1]heptan-2-one.

Oily liquid, miscible with ethanol (96 per cent), practically insoluble in water.

n_D^{20}: about 1.46.

bp_{15mm}: 192 °C to 194 °C.

Fenchone used in gas chromatography complies with the following test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Bitter fennel (0824)*.

Test solution. The substance to be examined.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Fenvalerate. $C_{25}H_{22}ClNO_3$. (M_r 419.9). *1127300.* [51630-58-1].

bp: about 300 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Ferric ammonium sulfate. $FeNH_4(SO_4)_2,12H_2O$. (M_r 482.2). *1037700.* [7783-83-7]. Ammonium iron disulfate dodecahydrate.

Pale-violet crystals, efflorescent, very soluble in water, practically insoluble in ethanol (96 per cent).

Ferric ammonium sulfate solution R2. *1037702.*

A 100 g/L solution. If necessary filter before use.

Ferric ammonium sulfate solution R5. *1037704.*

Shake 30.0 g of *ferric ammonium sulfate R* with 40 mL of *nitric acid R* and dilute to 100 mL with *water R*. If the solution is turbid, centrifuge or filter it.

Storage: protected from light.

Ferric ammonium sulfate solution R6. *1037705.*

Dissolve 20 g of *ferric ammonium sulfate R* in 75 mL of *water R*, add 10 mL of a 2.8 per cent *V/V* solution of *sulfuric acid R* and dilute to 100 mL with *water R*.

Ferric chloride. $FeCl_3,6H_2O$. (M_r 270.3). *1037800.* [10025-77-1]. Iron trichloride hexahydrate.

Yellowish-orange or brownish crystalline masses, deliquescent, very soluble in water, soluble in ethanol (96 per cent). On exposure to light, ferric chloride and its solutions are partly reduced.

Storage: in an airtight container.

Ferric chloride solution R1. *1037801.*

A 105 g/L solution.

Ferric chloride solution R2. *1037802.*

A 13 g/L solution.

Ferric chloride solution R3. *1037803.*

Dissolve 2.0 g of *ferric chloride R* in *anhydrous ethanol R* and dilute to 100.0 mL with the same solvent.

Ferric chloride-ferricyanide-arsenite reagent. *1037805.*

Immediately before use mix 10 mL of a 27 g/L solution of *ferric chloride R* in *dilute hydrochloric acid R*, 7 mL of *potassium ferricyanide solution R*, 3 mL of *water R* and 10 mL of *sodium arsenite solution R*.

Ferric chloride-sulfamic acid reagent. *1037804.*

A solution containing 10 g/L of *ferric chloride R* and 16 g/L of *sulfamic acid R*.

Ferric nitrate. $Fe(NO_3)_3,9H_2O$. (M_r 404). *1106100.* [7782-61-8].

Content: minimum 99.0 per cent *m/m* of $Fe(NO_3)_3,9H_2O$.

Light-purple crystals or crystalline mass, very soluble in water.

Free acid: not more than 0.3 per cent (as HNO_3).

Ferric sulfate. $Fe_2(SO_4)_3,xH_2O$. *1037900.* [10028-22-5]. Iron(III) trisulfate hydrated.

Yellowish-white powder, very hygroscopic, decomposes in air, slightly soluble in water and in ethanol (96 per cent).

Storage: in an airtight container, protected from light.

Ferric sulfate pentahydrate. $Fe_2(SO_4)_3,5H_2O$. (M_r 489.9). *1153700.* [142906-29-4].

White or yellowish powder.

Ferrocyphene. $C_{26}H_{16}FeN_6$. (M_r 468.3). *1038000.* [14768-11-7]. Dicyanobis(1,10-phenanthroline)iron(II).

Violet-bronze, crystalline powder, practically insoluble in water and in ethanol (96 per cent).

Storage: protected from light and moisture.

Ferroin. *1038100.* [14634-91-4].

Dissolve 0.7 g of *ferrous sulfate R* and 1.76 g of *phenanthroline hydrochloride R* in 70 mL of *water R* and dilute to 100 mL with the same solvent.

Test for sensitivity. To 50 mL of *dilute sulfuric acid R* add 0.15 mL of *osmium tetroxide solution R* and 0.1 mL of the ferroin. After the addition of 0.1 mL of *0.1 M ammonium and cerium nitrate* the colour changes from red to light blue.

Ferrous ammonium sulfate. $Fe(NH_4)_2(SO_4)_2,6H_2O$. (M_r 392.2). *1038200.* [7783-85-9]. Diammonium iron disulfate hexahydrate.

Pale bluish-green crystals or granules, freely soluble in water, practically insoluble in ethanol (96 per cent).

Storage: protected from light.

Ferrous sulfate. *1038300.* [7782-63-0].

See *Ferrous sulfate heptahydrate (0083).*

Ferrous sulfate solution R2. *1038301.*

Dissolve 0.45 g of *ferrous sulfate R* in 50 mL of *0.1 M hydrochloric acid* and dilute to 100 mL with *carbon dioxide-free water R*. Prepare immediately before use.

Ferulic acid. $C_{10}H_{10}O_4$. (M_r 194.2). *1149500.* [1135-24-6]. 4-Hydroxy-3-methoxycinnamic acid. 3-(4-Hydroxy-3-methoxyphenyl)propenoic acid.

Faint yellow powder, freely soluble in methanol.

mp: 172.9 °C to 173.9 °C.

Ferulic acid used in the assay of eleutherosides in Eleutherococcus (1419) complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Eleutherococcus (1419).*

Content: minimum 99 per cent, calculated by the normalisation procedure.

Fibrin blue. *1101400.*

Mix 1.5 g of fibrin with 30 mL of a 5 g/L solution of *indigo carmine R* in 1 per cent *V/V dilute hydrochloric acid R*. Heat the mixture to 80 °C and maintain at this temperature whilst stirring for about 30 min. Allow to cool. Filter. Wash extensively by resuspension in 1 per cent *V/V dilute hydrochloric acid R* and mixing for about 30 min; filter. Repeat the washing operation three times. Dry at 50 °C. Grind.

Fibrin congo red. *1038400.*

Take 1.5 g of fibrin and leave overnight in 50 mL of a 20 g/L solution of *congo red R* in *ethanol (90 per cent V/V) R*. Filter, rinse the fibrin with *water R* and store under *ether R*.

Fibrinogen. *1038500.* [9001-32-5].

See *Human fibrinogen, freeze-dried (0024).*

Fixing solution. *1122600.*

To 250 mL of *methanol R*, add 0.27 mL of *formaldehyde R* and dilute to 500.0 mL with *water R*.

Fixing solution for isoelectric focusing in polyacrylamide gel. *1138700.*

A solution containing 35 g of *sulfosalicylic acid R* and 100 g of *trichloroacetic acid R* per litre of *water R*.

Flufenamic acid. $C_{14}H_{10}F_3NO_2$. (M_r 281.2). *1106200.* [530-78-9]. 2-[[3-(Trifluoromethyl)phenyl]amino]benzoic acid.

Pale yellow, crystalline powder or needles, practically insoluble in water, freely soluble in ethanol (96 per cent).

mp: 132 °C to 135 °C.

Flumazenil. *1149600.* [78755-81-4].

See *Flumazenil (1326).*

Flunitrazepam. *1153800.* [1622-62-4].

See *Flunitrazepam (0717).*

Fluoranthene. $C_{16}H_{10}$. (M_r 202.3). *1038600.* [206-44-0]. 1,2-(1,8-Naphtylene)benzene. 1,2-Benzacenaphtene.

Yellow or yellowish-brown crystals.

bp: about 384 °C.

mp: 109 °C to 110 °C.

Fluorene. $C_{13}H_{10}$. (M_r 166.2). *1127400.* [86-73-7]. Diphenylenemethane.

White or almost white crystals, freely soluble in anhydrous acetic acid, soluble in hot ethanol (96 per cent).

mp: 113 °C to 115 °C.

Fluorescamine. $C_{17}H_{10}O_4$. (M_r 278.3). *1135800.* [38183-12-9]. 4-Phenylspiro[furan-2(3*H*),1'(3'*H*)-isobenzofuran]-3,3'-dione.

mp: 154 °C to 155 °C.

Fluorescein. $C_{20}H_{12}O_5$. (M_r 332.3). *1106300.* [2321-07-5]. 3′,6′-Dihydroxyspiro[isobenzofurane-1(3*H*),9′-[9*H*]xanthen]-3-one.

Orange-red powder, practically insoluble in water, soluble in warm ethanol (96 per cent), soluble in alkaline solutions. In solution, fluorescein displays a green fluorescence.

mp: about 315 °C.

Fluorescein-conjugated rabies antiserum. *1038700.*

Immunoglobulin fraction with a high rabies antibody titre, prepared from the sera of suitable animals that have been immunised with inactivated rabies virus; the immunoglobulin is conjugated with fluorescein isothiocyanate.

2-Fluoro-2-deoxy-D-glucose. $C_6H_{11}FO_5$. (M_r 182.2). *1113900.* [86783-82-6].

White or almost white crystalline powder.

mp: 174 °C to 176 °C.

2-Fluoro-2-deoxy-D-mannose. $C_6H_{11}FO_5$. (M_r 182.1). *1172100.* [38440-79-8].

Colourless semi-solid.

Fluorodinitrobenzene. $C_6H_3FN_2O_4$. (M_r 186.1). *1038800.* [70-34-8]. 1-Fluoro-2,4-dinitrobenzene.

Pale yellow crystals, soluble in propylene glycol.

mp: about 29 °C.

DL-6-Fluorodopa hydrochloride. $C_9H_{11}ClFNO_4$. (M_r 251.6). *1169200.* (2*RS*)-2-Amino-3-(2-fluoro-4,5-dihydroxyphenyl)propanoic acid hydrochloride. 2-Fluoro-5-hydroxy-DL-tyrosine hydrochloride.

White or almost white powder.

6-Fluorolevodopa hydrochloride. $C_9H_{11}ClFNO_4$. (M_r 251.6). *1169300.* [144334-59-8]. (2*S*)-2-Amino-3-(2-fluoro-4,5-dihydroxyphenyl)propanoic acid hydrochloride. 2-Fluoro-5-hydroxy-L-tyrosine hydrochloride.

Colourless or almost colourless solid, soluble in water.

1-Fluoro-2-nitro-4-(trifluoromethyl)benzene. $C_7H_3F_4NO_2$. (M_r 209.1). *1038900.* [367-86-2].

mp: about 197 °C.

Folic acid. *1039000.* [75708-92-8].

See *Folic acid (0067).*

Formaldehyde. *1039100.* [50-00-0].

See *Formaldehyde solution R.*

Formaldehyde solution. *1039101.*

See *Formaldehyde solution (35 per cent) (0826).*

Formamide. CH_3NO. (M_r 45.0). *1039200.* [75-12-7].

Clear, colourless, oily liquid, hygroscopic, miscible with water and with ethanol (96 per cent). It is hydrolysed by water.

d_{20}^{20}: about 1.134.

bp: about 210 °C.

Content: minimum 99.5 per cent.

Storage: in an airtight container.

Formamide R1. *1039202.*

Complies with the requirements prescribed for *formamide R* with the following additional requirement.

Water (*2.5.12*): maximum 0.1 per cent determined with an equal volume of *anhydrous methanol R*.

Formamide, treated. *1039201.*

Disperse 1.0 g of *sulfamic acid R* in 20.0 mL of *formamide R* containing 5 per cent *V/V* of *water R*.

Formic acid, anhydrous. CH_2O_2. (M_r 46.03). *1039300.* [64-18-6].

Content: minimum 98.0 per cent *m/m*.

Colourless liquid, corrosive, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: about 1.22.

Assay. Weigh accurately a conical flask containing 10 mL of *water R*, quickly add about 1 mL of the acid and weigh again. Add 50 mL of *water R* and titrate with *1 M sodium hydroxide*, using 0.5 mL of *phenolphthalein solution R* as indicator.

1 mL of *1 M sodium hydroxide* is equivalent to 46.03 mg of CH_2O_2.

Fructose. *1106400.* [57-48-7].

See *Fructose (0188)*.

Fuchsin, basic. *1039400.* [632-99-5].

A mixture of rosaniline hydrochloride ($C_{20}H_{20}ClN_3$; M_r 337.9; Colour Index No. 42510; Schultz No. 780) and *para*-rosaniline hydrochloride ($C_{19}H_{18}ClN_3$; M_r 323.8; Colour Index No. 42500; Schultz No. 779).

If necessary, purify in the following manner. Dissolve 1 g in 250 mL of *dilute hydrochloric acid R*. Allow to stand for 2 h at room temperature, filter and neutralise with *dilute sodium hydroxide solution R* and add 1 mL to 2 mL in excess. Filter the precipitate through a sintered-glass filter (40) (*2.1.2*) and wash with *water R*. Dissolve the precipitate in 70 mL of *methanol R*, previously heated to boiling, and add 300 mL of *water R* at 80 °C. Allow to cool to room temperature, filter and dry the crystals *in vacuo*.

Crystals with a greenish-bronze sheen, soluble in water and in ethanol (96 per cent).

Storage: protected from light.

Fuchsin solution, decolorised. *1039401.*

Dissolve 0.1 g of *basic fuchsin R* in 60 mL of *water R*. Add a solution containing 1 g of *anhydrous sodium sulfite R* or 2 g of *sodium sulfite R* in 10 mL of *water R*. Slowly and with continuous shaking add 2 mL of *hydrochloric acid R*. Dilute to 100 mL with *water R*. Allow to stand protected from light for at least 12 h, decolorise with *activated charcoal R* and filter. If the solution becomes cloudy, filter before use. If on standing the solution becomes violet, decolorise again by adding *activated charcoal R*.

Test for sensitivity. To 1.0 mL add 1.0 mL of *water R* and 0.1 mL of *aldehyde-free alcohol R*. Add 0.2 mL of a solution containing 0.1 g/L of formaldehyde (CH_2O, M_r 30.0). A pale-pink colour develops within 5 min.

Storage: protected from light.

Fuchsin solution, decolorised R1. *1039402.*

To 1 g of *basic fuchsin R* add 100 mL of *water R*. Heat to 50 °C and allow to cool with occasional shaking. Allow to stand for 48 h, shake and filter. To 4 mL of the filtrate add 6 mL of *hydrochloric acid R*, mix and dilute to 100 mL with *water R*. Allow to stand for at least 1 h before use.

Fucose. $C_6H_{12}O_5$. (M_r 164.2). *1039500.* [6696-41-9]. 6-Deoxy-L-galactose.

White or almost white powder, soluble in water and in ethanol (96 per cent).

$[\alpha]_D^{20}$: about – 76, determined on a 90 g/L solution 24 h after dissolution.

mp: about 140 °C.

Fumaric acid. $C_4H_4O_4$. (M_r 116.1). *1153200.* [110-17-8]. (*E*)-Butenedioic acid.

White or almost white crystals, slightly soluble in water, soluble in ethanol (96 per cent), slightly soluble in acetone.

mp: about 300 °C.

Furfural. $C_5H_4O_2$. (M_r 96.1). *1039600.* [98-01-1]. 2-Furaldehyde. 2-Furanecarbaldehyde.

Clear, colourless to brownish-yellow, oily liquid, miscible in 11 parts of water, miscible with ethanol (96 per cent).

d_{20}^{20}: 1.155 to 1.161.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 159 °C and 163 °C.

Storage: in a dark place.

Galactose. $C_6H_{12}O_6$. (M_r 180.2). *1039700.* [59-23-4]. D-(+)-Galactose.

White or almost white, crystalline powder, freely soluble in water.

$[\alpha]_D^{20}$: + 79 to + 81, determined on a 100 g/L solution in *water R* containing about 0.05 per cent of NH_3.

Gallic acid. $C_7H_6O_5,H_2O$. (M_r 188.1). *1039800.* [5995-86-8]. 3,4,5-Trihydroxybenzoic acid monohydrate.

Crystalline powder or long needles, colourless or slightly yellow, soluble in water, freely soluble in hot water, in ethanol (96 per cent) and in glycerol.

It loses its water of crystallisation at 120 °C.

mp: about 260 °C, with decomposition.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Bearberry leaf (1054)*; the chromatogram shows only one principal spot.

Gastric juice, artificial. *1039900.*

Dissolve 2.0 g of *sodium chloride R* and 3.2 g of *pepsin powder R* in *water R*. Add 80 mL of *1 M hydrochloric acid* and dilute to 1000 mL with *water R*.

GC concentrical column. *1135100.*

A commercially available system consisting of 2 concentrically arranged tubes. The outer tube is packed with molecular sieves and the inner tube is packed with a porous polymer mixture. The main application is the separation of gases.

Gelatin. *1040000.* [9000-70-8].

See *Gelatin (0330)*.

Gelatin, hydrolysed. *1040100.*

Dissolve 50 g of *gelatin R* in 1000 mL of *water R*. Autoclave in saturated steam at 121 °C for 90 min and freeze dry.

Geraniol. $C_{10}H_{18}O$. (M_r 154.2). *1135900.* [106-24-1]. (*E*)-3,7-Dimethylocta-2,6-dien-1-ol.

Oily liquid, slight odour of rose, practically insoluble in water, miscible with ethanol (96 per cent).

Geraniol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Citronella oil (1609)*.

Content: minimum 98.5 per cent, calculated by the normalisation procedure.

Storage: in an airtight container, protected from light

Geranyl acetate. $C_{12}H_{20}O_2$. (M_r 196.3). *1106500.* [105-87-3]. (*E*)-3,7-Dimethylocta-2,6-dien-1-yl acetate.

Colourless or slightly yellow liquid, slight odour of rose and lavender.

Geranyl acetate used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Bitter-orange-flower oil (1175)*.

Test solution. The substance to be examined.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Ginsenoside Rb1. $C_{54}H_{92}O_{23},3H_2O$. (M_r 1163). *1127500.* [41753-43-9]. (20*S*)-3β-di-D-Glucopyranosyl-20-di-D-glucopyranosylprotopanaxadiol. (20*S*)-3β-[(2-*O*-β-D-Glucopyranosyl-β-D-glucopyranosyl)oxy]-20-[(6-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]-5α-dammar-24-en-12β-ol. (20*S*)-3β-[(2-*O*-β-D-Glucopyranosyl-β-D-glucopyranosyl)oxy]-20-[(6-*O*-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]-4,4,8,14-tetramethyl-18-nor-5α-cholest-24-en-12β-ol.

A colourless solid, soluble in water, in anhydrous ethanol and in methanol.

$[\alpha]_D^{20}$: + 11.3 determined on a 10 g/L solution in *methanol R*.

mp: about 199 °C.

Water (2.5.12): maximum 6.8 per cent.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Ginseng (1523)*.

Test solution. Dissolve 3.0 mg, accurately weighted, of *ginsenoside Rb1* in 10 mL of *methanol R*.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Ginsenoside Re. $C_{48}H_{82}O_{18}$. (M_r 947.2). *1157800.* [52286-59-6]. (3β,6α,12β)-20-(β-D-Glucopyranosyloxy)-3,12-dihydroxydammar-24-en-6-yl 2-*O*-(6-deoxy-α-L-mannopyranosyl)-β-D-glucopyranoside.

Colourless solid, soluble in water, in ethanol (96 per cent) and in methanol.

Ginsenoside Rf. $C_{42}H_{72}O_{14},2H_2O$. (M_r 837). *1127700.* [52286-58-5]. (20*S*)-6-*O*-[β-D-Glucopyranosyl-(1→2)-β-D-glycopyranoside]-dammar-24-ene-3β,6α,12β,20-tetrol.

A colourless solid, soluble in water, in anhydrous ethanol and in methanol.

$[\alpha]_D^{20}$: + 12.8 determined on a 10 g/L solution in *methanol R*.

mp: about 198 °C.

Ginsenoside Rg1. $C_{42}H_{72}O_{14},2H_2O$. (M_r 837). *1127600.* [22427-39-0]. (20*S*)-6β-D-Glucopyranosyl-D-glucopyranosylprotopanaxatriol. (20*S*)-6α,20-bis(β-D-Glucopyranosyloxy)-5α-dammar-24-ene-3β,12β-diol. (20*S*)-6α,20-bis(β-D-Glucopyranosyloxy)-4,4,8,14-tetramethyl-18-nor-5α-cholest-24-ene-3β,12β-diol.

A colourless solid, soluble in water, in anhydrous ethanol and in methanol.

$[\alpha]_D^{20}$: + 31.2 determined on a 10 g/L solution in *methanol R*.

mp: 188 °C to 191 °C.

Water (2.5.12): maximum 4.8 per cent.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Ginseng (1523)*.

Test solution. Dissolve 3.0 mg, accurately weighted, of *ginsenoside Rg1* in 10 mL of *methanol R*.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Gitoxin. $C_{41}H_{64}O_{14}$. (M_r 781). *1040200.* [4562-36-1]. Glycoside of *Digitalis purpurea* L. 3β-(*O*-2,6-Dideoxy-β-d-*ribo*-hexopyranosyl-(1→4)-*O*-2,6-dideoxy-β-d-*ribo*-hexopyranosyl-(1→4)-2,6-dideoxy-β-d-*ribo*-hexopyranosyloxy)-14,16β-dihydroxy-5β,14β-card-20(22)-enolide.

A white or almost white, crystalline powder, practically insoluble in water and in most common organic solvents, soluble in pyridine.

$[\alpha]_D^{20}$: + 20 to + 24, determined on a 5 g/L solution in a mixture of equal volumes of *chloroform R* and *methanol R*.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Digitalis leaf (0117)*; the chromatogram shows only one principal spot.

Glucosamine hydrochloride. $C_6H_{14}ClNO_5$. (M_r 215.6). *1040300.* [66-84-2]. D-Glucosamine hydrochloride.

Crystals, soluble in water.

$[\alpha]_D^{20}$: + 100, decreasing to + 47.5 after 30 min, determined on a 100 g/L solution.

Glucose. *1025700.* [50-99-7].

See *Anhydrous glucose (0177)*.

D-Glucuronic acid. $C_6H_{10}O_7$. (M_r 194.1). *1119700.* [6556-12-3].

Content: minimum 96.0 per cent, calculated with reference to the substance dried *in vacuo* (*2.2.32*).

Soluble in water and in ethanol (96 per cent).

Shows mutarotation: $[\alpha]_D^{24}$: + 11.7 → + 36.3.

Assay. Dissolve 0.150 g in 50 mL of *anhydrous methanol R* while stirring under nitrogen. Titrate with *0.1 M tetrabutylammonium hydroxide*, protecting the solution from atmospheric carbon dioxide throughout solubilisation and titration. Determine the end-point potentiometrically (*2.2.20*).

1 mL of *0.1 M tetrabutylammonium hydroxide* is equivalent to 19.41 mg of $C_6H_{10}O_7$.

Glutamic acid. *1040400.* [56-86-0].

See *Glutamic acid (0750)*.

Glutamyl endopeptidase for peptide mapping. *1173300.* [137010-42-5]. Endoproteinase Glu-C of high purity from *Staphylococcus aureus* strain V8 (EC 3.4.21.19).

L-γ-Glutamyl-L-cysteine. $C_8H_{14}N_2O_5S$. (M_r 250.3). *1157900.* [636-58-8].

Glutaraldehyde. $C_5H_8O_2$. (M_r 100.1). *1098300.* [111-30-8].

Oily liquid, soluble in water.

n_D^{25}: about 1.434.

bp: about 188 °C.

Glutaric acid. $C_5H_8O_4$. (M_r 132.1). *1149700.* [110-94-1]. Pentanedioic acid.

White or almost white, crystalline powder.

L-Glutathione, oxidised. $C_{20}H_{32}N_6O_{12}S_2$. (M_r 612.6). *1158000.* [27025-41-8]. Bis(L-γ-glutamyl-L-cysteinylglycine) disulfide.

Glycerol. *1040500.* [56-81-5].

See *Glycerol (0496)*.

Glycerol R1. *1040501.*

Complies with the requirements prescribed for the monograph *Glycerol (0496)* and free from diethylene glycol when examined as prescribed in the test for Impurity A and related substances in that monograph.

Glycerol (85 per cent). *1040600.*

See *Glycerol (85 per cent) (0497)*.

Glycerol (85 per cent) R1. *1040601.*

Complies with the requirements prescribed for the monograph *Glycerol 85 per cent (0497)* and free from diethylene glycol when examined as prescribed in the test for Impurity A and related substances in that monograph.

Glycerol 1-decanoate. $C_{13}H_{26}O_4$. (M_r 246.3). *1169400.* [2277-23-8]. (2*RS*)-2,3-Dihydroxypropyl decanoate. α-Monocaprin. 1-Monodecanoyl-*rac*-glycerol.

Content: about 99 per cent.

Glycerol 1-octanoate. $C_{11}H_{22}O_4$. (M_r 218.3). *1169500.* [502-54-5]. (2*RS*)-2,3-Dihydroxypropyl octanoate. α-Monocaprylin. 1-Monooctanoyl-*rac*-glycerol.

Content: about 99 per cent.

Glycidol. $C_3H_6O_2$. (M_r 74.1). *1127800.* [556-52-5].

Slightly viscous liquid, miscible with water.

d_4^{20}: about 1.115.

n_D^{20}: about 1.432.

Glycine. *1040700.* [56-40-6].

See *Glycine (0614).*

Glycollic acid. $C_2H_4O_3$. (M_r 76.0). *1040800.* [79-14-1]. 2-Hydroxyacetic acid.

Crystals, soluble in water, in acetone, in ethanol (96 per cent) and in methanol.

mp: about 80 °C.

Glycyrrhetic acid. $C_{30}H_{46}O_4$. (M_r 470.7). *1040900.* [471-53-4]. Glycyrrhetinic acid. 12,13-Didehydro-3β-hydroxy-11-oxo-olean-30-oic acid.

A mixture of α- and β-glycyrrhetic acids in which the β-isomer is predominant.

White or yellowish-brown powder, practically insoluble in water, soluble in anhydrous ethanol and in glacial acetic acid.

$[\alpha]_D^{20}$: + 145 to + 155, determined on a 10.0 g/L solution in *anhydrous ethanol R*.

Chromatography. Thin-layer chromatography (*2.2.27*) using *silica gel* GF_{254} *R* as the coating substance; prepare the slurry using a 0.25 per cent *V/V* solution of *phosphoric acid R*. Apply to the plate 5 µL of a 5 g/L solution of the glycyrrhetic acid in a mixture of equal volumes of *chloroform R* and *methanol R*. Develop over a path of 10 cm using a mixture of 5 volumes of *methanol R* and 95 volumes of *chloroform R*. Examine the chromatogram in ultraviolet light at 254 nm. The chromatogram shows a dark spot (R_F about 0.3) corresponding to β-glycyrrhetic acid and a smaller spot (R_F about 0.5) corresponding to α-glycyrrhetic acid. Spray with *anisaldehyde solution R* and heat at 100-105 °C for 10 min. Both spots are coloured bluish-violet. Between them a smaller bluish-violet spot may be present.

18α-Glycyrrhetinic acid. $C_{30}H_{46}O_4$. (M_r 470.7). *1127900.* [1449-05-4]. (20β)-3β-Hydroxy-11-oxo-18α-olean-12-en-29-oic acid.

White or almost white powder, practically insoluble in water, soluble in anhydrous ethanol, sparingly soluble in methylene chloride.

Glyoxalhydroxyanil. $C_{14}H_{12}N_2O_2$. (M_r 240.3). *1041000.* [1149-16-2]. Glyoxal bis(2-hydroxyanil).

White or almost white crystals, soluble in hot ethanol (96 per cent).

mp: about 200 °C.

Glyoxal solution. *1098400.* [107-22-2].

Contains about 40 per cent (*m/m*) glyoxal.

Assay. In a ground-glass stoppered flask place 1.000 g of glyoxal solution, 20 mL of a 70 g/L solution of *hydroxylamine hydrochloride R* and 50 mL of *water R*. Allow to stand for 30 min and add 1 mL of *methyl red mixed solution R* and titrate with *1 M sodium hydroxide* until the colour changes from red to green. Carry out a blank titration.

1 mL of *1 M sodium hydroxide* is equivalent to 29.02 mg of glyoxal ($C_2H_2O_2$).

Gonadotrophin, chorionic. *1041100.* [9002-61-3].

See *Chorionic gonadotrophin (0498).*

Gonadotrophin, serum. *1041200.*

See *Equine serum gonadotrophin for veterinary use (0719).*

Guaiacol. $C_7H_8O_2$. (M_r 124.1). *1148300.* [90-05-1]. 2-Methoxyphenol. 1-Hydroxy-2-methoxybenzene.

Crystalline mass or colourless or yellowish liquid, hygroscopic, slightly soluble in water, very soluble in methylene chloride, freely soluble in ethanol (96 per cent).

bp: about 205 °C.

mp: about 28 °C.

Guaiacum resin. *1041400.*

Resin obtained from the heartwood of *Guaiacum officinale* L. and *Guaiacum sanctum* L.

Reddish-brown or greenish-brown, hard, glassy fragments; fracture shiny.

Guaiazulene. $C_{15}H_{18}$. (M_r 198.3). *1041500.* [489-84-9]. 1,4-Dimethyl-7-isopropylazulene.

Dark-blue crystals or blue liquid, very slightly soluble in water, miscible with fatty and essential oils and with liquid paraffin, sparingly soluble in ethanol (96 per cent), soluble in 500 g/L sulfuric acid and 80 per cent *m/m* phosphoric acid, giving a colourless solution.

mp: about 30 °C.

Storage: protected from light and air.

Guanidine hydrochloride. CH_5N_3HCl. (M_r 95.5). *1098500.* [50-01-1].

Crystalline powder, freely soluble in water and in ethanol (96 per cent).

Guanine. $C_5H_5N_5O$. (M_r 151.1). *1041600.* [73-40-5]. 2-Amino-1,7-dihydro-6*H*-purin-6-one.

Amorphous white or almost white powder, practically insoluble in water, slightly soluble in ethanol (96 per cent). It dissolves in ammonia and in dilute solutions of alkali hydroxides.

Haemoglobin. *1041700.* [9008-02-0].

Nitrogen: 15 per cent to 16 per cent.

Iron: 0.2 per cent to 0.3 per cent.

Loss on drying (*2.2.32*): maximum 2 per cent.

Sulfated ash (*2.4.14*): maximum 1.5 per cent.

Haemoglobin solution. *1041701.*

Transfer 2 g of *haemoglobin R* to a 250 mL beaker and add 75 mL of *dilute hydrochloric acid R2*. Stir until solution is complete. Adjust the pH to 1.6 ± 0.1 using *1 M hydrochloric acid*. Transfer to a 100 mL flask with the aid of *dilute hydrochloric acid R2*. Add 25 mg of *thiomersal R*. Prepare daily, store at 5 ± 3 °C and readjust to pH 1.6 before use.

Storage: at 2 °C to 8 °C.

Harpagoside. $C_{24}H_{30}O_{11}$. (M_r 494.5). *1098600.*

White or almost white, crystalline powder, very hygroscopic, soluble in water and in ethanol (96 per cent).

mp: 117 °C to 121 °C.

Storage: in an airtight container.

Hederacoside C. $C_{59}H_{96}O_{26}$. (M_r 1221). *1158100.* [14216-03-6]. *O*-6-Deoxy-α-L-mannopyranosyl-(1→4)-*O*-β-D-glucopyranosyl-(1→6)-β-D-glucopyranosyl (4*R*)-3β-[[2-*O*(-6-deoxy-α-L-mannopyranosyl)-α-L-arabinopyranosyl]oxy]-23-hydroxyolean-12-en-28-oate.

Colourless crystals or white or almost white powder.

mp: about 220 °C.

Hederacoside C used in liquid chromatography complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Ivy leaf (2148).*

Test solution. Dissolve 5.0 mg of hederacoside C in 5.0 mL of *methanol R*.

Content: minimum 95 per cent, calculated by the normalisation procedure.

α-Hederin. $C_{41}H_{66}O_{12}$. (M_r 751.0). *1158200.* [27013-91-8]. (+)-(4*R*)-3β-[[2-*O*-(6-Deoxy-α-L-mannopyranosyl)-α-L-arabinopyranosyl]oxy]-23-hydroxyolean-12-en-28-oic acid.

White or almost white powder.

mp: about 256 °C.

Helium for chromatography. He. (A_r 4.003). *1041800.* [7440-59-7].
Content: minimum 99.995 per cent *V/V* of He.

Heparin. *1041900.* [9041-08-1].
See *Heparin sodium (0333).*

Heptachlor. $C_{10}H_5Cl_7$. (M_r 373.3). *1128000.* [76-44-8].
bp: about 135 °C.
mp: about 95 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Heptachlor epoxide. $C_{10}H_5Cl_7O$. (M_r 389.3). *1128100.* [1024-57-3].
bp: about 200 °C.
mp: about 160 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Heptafluorobutyric acid. $C_4HF_7O_2$. (M_r 214.0). *1162400.* [375-22-4]. HFBA.
Clear, colourless liquid. Corrosive.
d_{20}^{20}: about 1.645.
n_D^{20}: about 1.300.
bp: about 120 °C.
Content: minimum 99.5 per cent.

Heptafluoro-*N*-methyl-*N*-(trimethylsilyl)butanamide. $C_8H_{12}F_7NOSi$. (M_r 299.3). *1139500.* [53296-64-3]. 2,2,3,3,4,4,4-Heptafluoro-*N*-methyl-*N*-(trimethylsilyl)butyramide.
Clear, colourless liquid, flammable.
n_D^{20}: about 1.351.
bp: about 148 °C.

Heptane. C_7H_{16}. (M_r 100.2). *1042000.* [142-82-5].
Colourless, flammable liquid, practically insoluble in water, miscible with anhydrous ethanol.
d_{20}^{20}: 0.683 to 0.686.
n_D^{20}: 1.387 to 1.388.
Distillation range (*2.2.11*). Not less than 95 per cent distils between 97 °C and 98 °C.

Hesperidin. $C_{28}H_{34}O_{15}$. (M_r 611). *1139000.* [520-26-3]. (*S*)-7-[[6-*O*-(6-Deoxy-α-L-mannopyranosyl)-β-D-glucopyranosyl]oxy]-5-hydroxy-2-(3-hydroxy-4-methoxyphenyl)-2,3-dihydro-4*H*-1-benzopyran-4-one.
Hygroscopic powder, slightly soluble in water and in methanol.
mp: 258 °C to 262 °C.

Hexachlorobenzene. C_6Cl_6. (M_r 284.8). *1128200.* [118-74-1].
bp: about 332 °C.
mp: about 230 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

α-Hexachlorocyclohexane. $C_6H_6Cl_6$. (M_r 290.8). *1128300.* [319-84-6].
bp: about 288 °C.
mp: about 158 °C.
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

β-Hexachlorocyclohexane. $C_6H_6Cl_6$. (M_r 290.8). *1128400.* [319-85-7].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

δ-Hexachlorocyclohexane. $C_6H_6Cl_6$. (M_r 290.8). *1128500.* [319-86-8].
A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Hexacosane. $C_{26}H_{54}$. (M_r 366.7). *1042200.* [630-01-3].
Colourless or white or almost white flakes.
mp: about 57 °C.

Hexadimethrine bromide. $(C_{13}H_{30}Br_2N_2)_n$. *1042300.* [28728-55-4]. 1,5-Dimethyl-1,5-diazaundecamethylene polymethobromide. Poly(1,1,5,5-tetramethyl-1,5-azonia-undecamethylene dibromide).
White or almost white, amorphous powder, hygroscopic, soluble in water.
Storage: in an airtight container.

2,2′,2″,6,6′,6″-Hexa(1,1-dimethylethyl)-4,4′,4″-[(2,4,6-trimethyl-1,3,5-benzenetriyl)trismethylene]triphenol. $C_{54}H_{78}O_3$. (M_r 775). *1042100.* 2,2′,2″,6,6′,6″-Hexa-*tert*-butyl-4,4′,4″-[(2,4,6-trimethyl-1,3,5-benzenetriyl)trismethylene]triphenol.
Crystalline powder, practically insoluble in water, soluble in acetone, slightly soluble in ethanol (96 per cent).
mp: about 244 °C.

1,1,1,3,3,3-Hexafluoropropan-2-ol. $C_3H_2F_6O$. (M_r 168.0). *1136000.* [920-66-1].
Content: minimum 99.0 per cent, determined by gas chromatography.
Clear, colourless liquid, miscible with water and with anhydrous ethanol.
d_{20}^{20}: about 1.596.
bp: about 59 °C.

Hexamethyldisilazane. $C_6H_{19}NSi_2$. (M_r 161.4). *1042400.* [999-97-3].
Clear, colourless liquid.
d_{20}^{20}: about 0.78.
n_D^{20}: about 1.408.
bp: about 125 °C.
Storage: in an airtight container.

Hexamethylenetetramine. $C_6H_{12}N_4$. (M_r 140.2). *1042500.* [100-97-0]. Hexamine. 1,3,5,7-Tetra-azatricyclo [3.3.1.1^{3,7}]decane.
Colourless, crystalline powder, very soluble in water.

Hexane. C_6H_{14}. (M_r 86.2). *1042600.* [110-54-3].
Colourless, flammable liquid, practically insoluble in water, miscible with anhydrous ethanol.
d_{20}^{20}: 0.659 to 0.663.
n_D^{20}: 1.375 to 1.376.
Distillation range (*2.2.11*). Not less than 95 per cent distils between 67 °C and 69 °C.
Hexane used in spectrophotometry complies with the following additional test.
Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 97 per cent from 260 nm to 420 nm.

Hexylamine. $C_6H_{15}N$. (M_r 101.2). *1042700.* [111-26-2]. Hexanamine.
Colourless liquid, slightly soluble in water, soluble in ethanol (96 per cent).
d_{20}^{20}: about 0.766.
n_D^{20}: about 1.418.
bp: 127 °C to 131 °C.

Histamine dihydrochloride. *1042800.* [56-92-8].
See *Histamine dihydrochloride (0143).*

Histamine phosphate. *1042900.* [23297-93-0].
See *Histamine phosphate (0144).*

Histamine solution. *1042901.*

A 9 g/L solution of *sodium chloride R* containing 0.1 µg per millilitre of histamine base (as the phosphate or dihydrochloride).

Histidine monohydrochloride. $C_6H_{10}ClN_3O_2,H_2O$. (M_r 209.6). *1043000.* [123333-71-1]. (*RS*)-2-Amino-3-(imidazol-4-yl)propionic acid hydrochloride monohydrate.

Crystalline powder or colourless crystals, soluble in water.

mp: about 250 °C, with decomposition.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Histamine dihydrochloride (0143)*; the chromatogram shows only one principal spot.

Holmium oxide. Ho_2O_3. (M_r 377.9). *1043100.* [12055-62-8]. Diholmium trioxide.

Yellowish powder, practically insoluble in water.

Holmium perchlorate solution. *1043101.*

A 40 g/L solution of *holmium oxide R* in a solution of *perchloric acid R* containing 141 g/L of $HClO_4$.

DL-Homocysteine. $C_4H_9NO_2S$. (M_r 135.2). *1136100.* [454-29-5]. (2*RS*)-2-Amino-4-sulfanylbutanoic acid.

White or almost white, crystalline powder.

mp: about 232 °C.

L-Homocysteine thiolactone hydrochloride. C_4H_8ClNOS. (M_r 153.6). *1136200.* [31828-68-9]. (3*S*)-3-Aminodihydrothiophen-2(3*H*)-one hydrochloride.

White or almost white, crystalline powder.

mp: about 202 °C.

Hyaluronidase diluent. *1043300.*

Mix 100 mL of *phosphate buffer solution pH 6.4 R* with 100 mL of *water R*. Dissolve 0.140 g of *hydrolysed gelatin R* in the solution at 37 °C.

Storage: use within 2 h.

Hydrastine hydrochloride. $C_{21}H_{22}ClNO_6$. (M_r 419.9). *1154000.* [5936-28-7]. (3*S*)-6,7-Dimethoxy-3-[(5*R*)-6-methyl-5,6,7,8-tetrahydro-1,3-dioxolo[4,5-*g*]isoquinolin-5-yl]isobenzofuran-1(3*H*)-one hydrochloride.

White or almost white powder, hygroscopic, very soluble in water and in ethanol (96 per cent).

$[\alpha]_D^{17}$: about + 127.

mp: about 116 °C.

Hydrastine hydrochloride used in liquid chromatography complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Goldenseal rhizome (1831)*.

Content: minimum 98 per cent, calculated by the normalisation procedure.

Hydrazine. H_4N_2. (M_r 32.05). *1136300.* [302-01-2]. Diazane.

Slightly oily liquid, colourless, with a strong odour of ammonia, miscible with water. Dilute solutions in water are commercially available.

n_D^{20}: about 1.470.

bp: about 113 °C.

mp: about 1.5 °C.

Caution: toxic and corrosive.

Hydrazine sulfate. $H_6N_2O_4S$. (M_r 130.1). *1043400.* [10034-93-2].

Colourless crystals, sparingly soluble in cold water, soluble in hot water (50 °C) and freely soluble in boiling water, practically insoluble in ethanol (96 per cent).

Arsenic (*2.4.2, Method A*): maximum 1 ppm, determined on 1.0 g.

Sulfated ash (*2.4.14*): maximum 0.1 per cent.

Hydriodic acid. HI. (M_r 127.9). *1098900.* [10034-85-2].

Prepare by distilling hydriodic acid over red phosphorus, passing *carbon dioxide R* or *nitrogen R* through the apparatus during the distillation. Use the colourless or almost colourless, constant-boiling mixture (55 per cent to 58 per cent of HI) distilling between 126 °C and 127 °C.

Place the acid in small, amber, glass-stoppered bottles previously flushed with *carbon dioxide R* or *nitrogen R*, seal with paraffin.

Storage: in a dark place.

Hydrobromic acid, 30 per cent. *1098700.* [10035-10-6].

A 30 per cent solution of hydrobromic acid in *glacial acetic acid R*.

Degas with caution the contents before opening.

Hydrobromic acid, dilute. *1098701.*

Place 5.0 mL of *30 per cent hydrobromic acid R* in amber vials equipped with polyethylene stoppers. Seal under *argon R* and store in the dark. Add 5.0 mL of *glacial acetic acid R* immediately before use. Shake.

Storage: in the dark.

Hydrobromic acid, 47 per cent. *1118900.*

A 47 per cent *m/m* solution of hydrobromic acid.

Hydrobromic acid, dilute R1. *1118901.*

Contains 7,9 g/L of HBr.

Dissolve 16.81 g of *47 per cent hydrobromic acid R* in *water R* and dilute to 1000 mL with the same solvent.

Hydrochloric acid. *1043500.* [7647-01-0].

See *Concentrated hydrochloric acid (0002)*.

2 M Hydrochloric acid. *3001700.*

Dilute 206.0 g of *hydrochloric acid R* to 1000.0 mL with *water R*.

3 M Hydrochloric acid. *3001600.*

Dilute 309.0 g of *hydrochloric acid R* to 1000.0 mL with *water R*.

6 M Hydrochloric acid. *3001500.*

Dilute 618.0 g of *hydrochloric acid R* to 1000.0 mL with *water R*.

Hydrochloric acid R1. *1043501.*

Contains 250 g/L of HCl.

Dilute 70 g of *hydrochloric acid R* to 100 mL with *water R*.

Hydrochloric acid, brominated. *1043507.*

To 1 mL of *bromine solution R* add 100 mL of *hydrochloric acid R*.

Hydrochloric acid, dilute. *1043503.*

Contains 73 g/L of HCl.

Dilute 20 g of *hydrochloric acid R* to 100 mL with *water R*.

Hydrochloric acid, dilute, heavy metal-free. *1043509.*

Complies with the requirements prescribed for *dilute hydrochloric acid R* with the following maximum contents of heavy metals.

As: 0.005 ppm.

Cd: 0.003 ppm.

Cu: 0.003 ppm.

Fe: 0.05 ppm.

Hg: 0.005 ppm.

Ni: 0.004 ppm.

Pb: 0.001 ppm.

Zn: 0.005 ppm.

Hydrochloric acid, dilute R1. *1043504.*

Contains 0.37 g/L of HCl.

Dilute 1.0 mL of *dilute hydrochloric acid R* to 200.0 mL with *water R*.

Hydrochloric acid, dilute R2. *1043505.*

Dilute 30 mL of *1 M hydrochloric acid* to 1000 mL with *water R*; adjust to pH 1.6 ± 0.1.

Hydrochloric acid, ethanolic. *1043506.*

Dilute 5.0 mL of *1 M hydrochloric acid* to 500.0 mL with *ethanol (96 per cent) R*.

Hydrochloric acid, heavy metal-free. *1043510.*

Complies with the requirements prescribed for *hydrochloric acid R* with the following maximum contents of heavy metals.

As: 0.005 ppm.

Cd: 0.003 ppm.

Cu: 0.003 ppm.

Fe: 0.05 ppm.

Hg: 0.005 ppm.

Ni: 0.004 ppm.

Pb: 0.001 ppm.

Zn: 0.005 ppm.

Hydrochloric acid, lead-free. *1043508.*

Complies with the requirements prescribed for *hydrochloric acid R* with the following additional requirement.

Lead: maximum 20 ppb.

Atomic emission spectrometry (*2.2.22, Method I*).

Test solution. In a quartz crucible evaporate 200 g of the acid to be examined almost to dryness. Take up the residue in 5 mL of nitric acid prepared by sub-boiling distillation of *nitric acid R* and evaporate to dryness. Take up the residue in 5 mL of nitric acid prepared by sub-boiling distillation of *nitric acid R*.

Reference solutions. Prepare the reference solutions using *lead standard solution (0.1 ppm Pb) R* diluted with nitric acid prepared by sub-boiling distillation of *nitric acid R*.

Wavelength: 220.35 nm.

Hydrochloric acid, methanolic. *1043511.*

Dilute 4.0 mL of *hydrochloric acid R* to 1000.0 mL with *methanol R2*.

Hydrocortisone acetate. *1098800.* [50-03-3].

See *Hydrocortisone acetate (0334)*.

Hydrofluoric acid. HF. (M_r 20.01). *1043600.* [7664-39-3].

Content: minimum 40.0 per cent *m/m*.

Clear, colourless liquid.

Loss on ignition: not more than 0.05 per cent *m/m*; evaporate the hydrofluoric acid in a platinum crucible and gently ignite the residue to constant mass.

Assay. Weigh accurately a glass-stoppered flask containing 50.0 mL of *1 M sodium hydroxide*. Introduce 2 g of the hydrofluoric acid and weigh again. Titrate the solution with *0.5 M sulfuric acid*, using 0.5 mL of *phenolphthalein solution R* as indicator.

1 mL of *1 M sodium hydroxide* is equivalent to 20.01 mg of HF.

Storage: in a polyethylene container.

Hydrogen for chromatography. H_2. (M_r 2.016). *1043700.* [1333-74-0].

Content: minimum 99.95 per cent *V/V*.

Hydrogen peroxide solution, dilute. *1043800.* [7722-84-1].

See *Hydrogen peroxide solution (3 per cent) (0395)*.

Hydrogen peroxide solution, strong. *1043900.* [7722-84-1].

See *Hydrogen peroxide solution (30 per cent) (0396)*.

Hydrogen sulfide. H_2S. (M_r 34.08). *1044000.* [7783-06-4].

Gas, slightly soluble in water.

Hydrogen sulfide solution. *1136400.*

A recently prepared solution of *hydrogen sulfide R* in *water R*. The saturated solution contains about 0.4 per cent to 0.5 per cent of H_2S at 20 °C.

Hydrogen sulfide R1. H_2S. (M_r 34.08). *1106600.* [7783-06-4].

Content: minimum 99.7 per cent *V/V*.

Hydroquinone. $C_6H_6O_2$. (M_r 110.1). *1044100.* [123-31-9].

Benzene-1,4-diol.

Fine, colourless or white or almost white needles, darkening on exposure to air and light, soluble in water and in ethanol (96 per cent).

mp: about 173 °C.

Storage: protected from light and air.

Hydroquinone solution. *1044101.*

Dissolve 0.5 g of *hydroquinone R* in *water R*, add 20 µL of *sulfuric acid R* and dilute to 50 mL with *water R*.

2-Hydroxybenzimidazole. $C_7H_6N_2O$. (M_r 134.1). *1169600.* [615-16-7]. 1*H*-benzimidazol-2-ol.

4-Hydroxybenzohydrazide. $C_7H_8N_2O_2$. (M_r 152.2). *1145900.* [5351-23-5]. *p*-Hydroxybenzohydrazide.

4-Hydroxybenzoic acid. $C_7H_6O_3$. (M_r 138.1). *1106700.* [99-96-7].

Crystals, slightly soluble in water, very soluble in ethanol (96 per cent), soluble in acetone.

mp: 214 °C to 215 °C.

4-Hydroxycoumarin. $C_9H_6O_3$. (M_r 162.2). *1169700.* [1076-38-6]. 4-Hydroxy-2*H*-1-benzopyran-2-one.

White or almost white powder, freely soluble in methanol.

Content: minimum 98.0 per cent.

6-Hydroxydopa. $C_9H_{11}NO_5$. (M_r 213.2). *1169800.* [21373-30-8]. (2*RS*)-2-Amino-3-(2,4,5-trihydroxyphenyl)propanoic acid. 2,5-Dihydroxy-DL-tyrosine.

mp: about 257 °C.

2-[4-(2-Hydroxyethyl)piperazin-1-yl]ethanesulfonic acid. $C_8H_{18}N_2O_4S$. (M_r 238.3). *1106800.* [7365-45-9]. HEPES.

White or almost white powder.

mp: about 236 °C, with decomposition

4-Hydroxyisophthalic acid. $C_8H_6O_5$. (M_r 182.1). *1106900.* [636-46-4]. 4-Hydroxybenzene-1,3-dicarboxylic acid.

Needles or platelets, very slightly soluble in water, freely soluble in ethanol (96 per cent).

mp: about 314 °C, with decomposition.

Hydroxylamine hydrochloride. NH_4ClO. (M_r 69.5). *1044300.* [5470-11-1].

White or almost white, crystalline powder, very soluble in water, soluble in ethanol (96 per cent).

Hydroxylamine hydrochloride solution R2. *1044304.*

Dissolve 2.5 g of *hydroxylamine hydrochloride R* in 4.5 mL of hot *water R* and add 40 mL of *ethanol (96 per cent) R* and 0.4 mL of *bromophenol blue solution R2*. Add *0.5 M alcoholic potassium hydroxide* until a greenish-yellow colour is obtained. Dilute to 50.0 mL with *ethanol (96 per cent) R*.

Hydroxylamine solution, alcoholic. *1044301.*

Dissolve 3.5 g of *hydroxylamine hydrochloride R* in 95 mL of *ethanol (60 per cent V/V) R*, add 0.5 mL of a 2 g/L solution of *methyl orange R* in *ethanol (60 per cent V/V) R* and sufficient *0.5 M potassium hydroxide in alcohol (60 per cent V/V)* to give a pure yellow colour. Dilute to 100 mL with *ethanol (60 per cent V/V) R*.

Hydroxylamine solution, alkaline. *1044302.*

Immediately before use, mix equal volumes of a 139 g/L solution of *hydroxylamine hydrochloride R* and a 150 g/L solution of *sodium hydroxide R*.

Hydroxylamine solution, alkaline R1. *1044303.*

Solution A. Dissolve 12.5 g of *hydroxylamine hydrochloride R* in *methanol R* and dilute to 100 mL with the same solvent.

Solution B. Dissolve 12.5 g of *sodium hydroxide R* in *methanol R* and dilute to 100 mL with the same solvent.

Mix equal volumes of solution A and solution B immediately before use.

Hydroxymethylfurfural. $C_6H_6O_3$. (M_r 126.1). *1044400.* [67-47-0]. 5-Hydroxymethylfurfural.

Acicular crystals, freely soluble in water, in acetone and in ethanol (96 per cent).

mp: about 32 °C.

Hydroxynaphthol blue, sodium salt. $C_{20}H_{11}N_2Na_3O_{11}S_3$. ($M_r$ 620). *1044500.* [63451-35-4]. Trisodium 2,2′-dihydroxy-1,1′-azonaphthalene-3′,4,6′-trisulfonate.

2-Hydroxypropylbetadex for chromatography R. *1146000.* Betacyclodextrin modified by the bonding of (*R*) or (*RS*) propylene oxide groups on the hydroxyl groups.

Hydroxypropyl-β-cyclodextrin. *1128600.* [94035-02-6].

See *Hydroxypropylbetadex (1804).*

pH (*2.2.3*): 5.0 to 7.5 for a 20 g/L solution.

Hydroxyquinoline. C_9H_7NO. (M_r 145.2). *1044600.* [148-24-3]. 8-Hydroxyquinoline. Quinolin-8-ol.

White or slightly yellowish, crystalline powder, slightly soluble in water, freely soluble in acetone, in ethanol (96 per cent) and in dilute mineral acids.

mp: about 75 °C.

Sulfated ash (*2.4.14*): maximum 0.05 per cent.

12-Hydroxystearic acid. $C_{18}H_{36}O_3$. (M_r 300.5). *1099000.* [106-14-9]. 12-Hydroxyoctadecanoic acid.

White or almost white powder.

mp: 71 °C to 74 °C.

5-Hydroxyuracil. $C_4H_4N_2O_3$. (M_r 128.1). *1044700.* [496-76-4]. Isobarbituric acid. Pyrimidine-2,4,5-triol.

White or almost white, crystalline powder.

mp: about 310 °C, with decomposition.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Fluorouracil (0611)*; the chromatogram shows a principal spot with an R_F of about 0.3.

Storage: in an airtight container.

Hyoscine hydrobromide. *1044800.* [6533-68-2].

See *Hyoscine hydrobromide (0106).*

Hyoscyamine sulfate. *1044900.* [620-61-1].

See *Hyoscyamine sulfate (0501).*

Hypericin. $C_{30}H_{16}O_8$. (M_r 504.4). *1149800.* [548-04-9]. 1,3,4,6,8,13-Hexahydroxy-10,11-dimethylphenanthro[1,10,9,8-*opqra*]perylene-7,14-dione.

Content: minimum 85 per cent.

Hyperoside. $C_{21}H_{20}O_{12}$. (M_r 464.4). *1045000.* 2-(3,4-Dihydroxyphenyl)-3-β-D-galactopyranosyloxy-5,7-dihydroxy-chromen-4-one.

Faint yellow needles, soluble in methanol.

$[\alpha]_D^{20}$: – 8.3, determined on a 2 g/L solution in *pyridine R*.

mp: about 240 °C, with decomposition.

Absorbance (*2.2.25*). A solution in *methanol R* shows two absorption maxima at 259 nm and at 364 nm.

Hypophosphorous reagent. *1045200.*

Dissolve with the aid of gentle heat, 10 g of *sodium hypophosphite R* in 20 mL of *water R* and dilute to 100 mL with *hydrochloric acid R*. Allow to settle and decant or filter through glass wool.

Hypoxanthine. $C_5H_4N_4O$. (M_r 136.1). *1045300.* [68-94-0]. 1*H*-Purin-6-one.

White or almost white, crystalline powder, very slightly soluble in water, sparingly soluble in boiling water, soluble in dilute acids and in dilute alkali hydroxide solutions, decomposes without melting at about 150 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Mercaptopurine (0096)*; the chromatogram shows only one principal spot.

Imidazole. $C_3H_4N_2$. (M_r 68.1). *1045400.* [288-32-4].

White or almost white, crystalline powder, soluble in water and in ethanol (96 per cent).

mp: about 90 °C.

Iminodibenzyl. $C_{14}H_{13}N$. (M_r 195.3). *1045500.* [494-19-9]. 10,11-Dihydrodibenz[*b,f*]azepine.

Pale yellow, crystalline powder, practically insoluble in water, freely soluble in acetone.

mp: about 106 °C.

2-Indanamine hydrochloride. $C_9H_{12}ClN$. (M_r 169.7). *1175800.* [2338-18-3]. 2-Aminoindane hydrochloride.

2,3-Dihydro-1*H*-inden-2-amine hydrochloride.

Indigo carmine. $C_{16}H_8N_2Na_2O_8S_2$. (M_r 466.3). *1045600.* [860-22-0].

Schultz No. 1309.

Colour Index No. 73015.

3,3′-Dioxo-2,2′-bisindolylidene-5,5′-disulfonate disodium. E 132.

It usually contains sodium chloride.

Blue or violet-blue powder or blue granules with a coppery lustre, sparingly soluble in water, practically insoluble in ethanol (96 per cent). It is precipitated from an aqueous solution by sodium chloride.

Indigo carmine solution. *1045601.*

To a mixture of 10 mL of *hydrochloric acid R* and 990 mL of 200 g/L *nitrogen-free sulfuric acid R* add 0.2 g of *indigo carmine R*.

The solution complies with the following test: add 10 mL to a solution of 1.0 mg of *potassium nitrate R* in 10 mL of *water R*, rapidly add 20 mL of *nitrogen-free sulfuric acid R* and heat to boiling. The blue colour is discharged within 1 min.

Indigo carmine solution R1. *1045602.*

Dissolve 4 g of *indigo carmine R* in about 900 mL of *water R* added in several portions. Add 2 mL of *sulfuric acid R* and dilute to 1000 mL with *water R*.

Assay. Place in a 100 mL conical flask with a wide neck 10.0 mL of *nitrate standard solution (100 ppm NO_3) R*, 10 mL of *water R*, 0.05 mL of the *indigo carmine solution R1*, and then in a single addition, but with caution, 30 mL of *sulfuric acid R*. Titrate the solution immediately, using the *indigo carmine solution R1*, until a stable blue colour is obtained.

The number of millilitres used, *n*, is equivalent to 1 mg of NO_3.

Indometacin. *1101500.* [53-86-1].

See *Indometacin (0092).*

Inosine. $C_{10}H_{12}N_4O_5$. (M_r 268.2). *1169900.* [58-63-9]. 9-β-D-Ribofuranosylhypoxanthine. 9-β-D-Ribofuranosyl-1,9-dihydro-6*H*-purin-6-one.

mp: 222 °C to 226 °C.

***myo*-Inositol.** *1161100.*

See *myo-Inositol (1805).*

Iodine. *1045800.* [7553-56-2].

See *Iodine (0031).*

Iodine solution R1. *1045801.*

To 10.0 mL of *0.05 M iodine* add 0.6 g of *potassium iodide R* and dilute to 100.0 mL with *water R*. Prepare immediately before use.

Iodine solution R2. *1045802.*

To 10.0 mL of *0.05 M iodine* add 0.6 g of *potassium iodide R* and dilute to 1000.0 mL with *water R*. Prepare immediately before use.

Iodine solution R3. *1045803.*

Dilute 2.0 mL of *iodine solution R1* to 100.0 mL with *water R*. Prepare immediately before use.

Iodine solution R4. *1045806.*

Dissolve 14 g of *iodine R* in 100 mL of a 400 g/L solution of *potassium iodide R*, add 1 mL of *dilute hydrochloric acid R* and dilute to 1000 mL with *water R*.

Storage: protected from light.

Iodine solution, alcoholic. *1045804.*

A 10 g/L solution in *ethanol (96 per cent) R*.

Storage: protected from light.

Iodine solution, chloroformic. *1045805.*

A 5 g/L solution in *chloroform R*.

Storage: protected from light.

Iodine-123 and ruthenium-106 spiking solution. *1166700.*

Prepare immediately before use. Mix 3.5 mL of an 18.5 kBq/mL solution of ruthenium-106 in the form of ruthenium trichloride in a mixture of equal volumes of *glacial acetic acid R* and *water R* with 200 µL of a 75 kBq/mL solution of iodine-123 in the form of sodium iodide in *water R*.

Iodine bromide. IBr. (M_r 206.8). *1045900.* [7789-33-5].

Bluish-black or brownish-black crystals, freely soluble in water, in ethanol (96 per cent) and in glacial acetic acid.

bp: about 116 °C.

mp: about 40 °C.

Storage: protected from light.

Iodine bromide solution. *1045901.*

Dissolve 20 g of *iodine bromide R* in *glacial acetic acid R* and dilute to 1000 mL with the same solvent.

Storage: protected from light.

Iodine chloride. ICl. (M_r 162.4). *1143000.* [7790-99-0].

Black crystals, soluble in water, in acetic acid and in ethanol (96 per cent).

bp: about 97.4 °C.

Iodine chloride solution. *1143001.*

Dissolve 1.4 g of *iodine chloride R* in *glacial acetic acid R* and dilute to 100 mL with the same acid.

Storage: protected from light.

Iodine pentoxide, recrystallised. I_2O_5. (M_r 333.8). *1046000.* [12029-98-0]. Di-iodine pentoxide. Iodic anhydride.

Content: minimum 99.5 per cent.

White or almost white, crystalline powder, or white or greyish-white granules, hygroscopic, very soluble in water forming HIO_3.

Stability on heating. Dissolve 2 g, previously heated for 1 h at 200 °C, in 50 mL of *water R*. A colourless solution is obtained.

Assay. Dissolve 0.100 g in 50 mL of *water R*, add 3 g of *potassium iodide R* and 10 mL of *dilute hydrochloric acid R*. Titrate the liberated iodine with *0.1 M sodium thiosulfate*, using 1 mL of *starch solution R* as indicator.

1 mL of *0.1 M sodium thiosulfate* is equivalent to 2.782 mg of I_2O_5.

Storage: in an airtight container, protected from light.

Iodoacetic acid. $C_2H_3IO_2$. (M_r 185.9). *1107000.* [64-69-7].

Colourless or white or almost white crystals, soluble in water and in ethanol (96 per cent).

mp: 82 °C to 83 °C.

2-Iodobenzoic acid. $C_7H_5IO_2$. (M_r 248.0). *1046100.* [88-67-5].

White or slightly yellow, crystalline powder, slightly soluble in water, soluble in ethanol (96 per cent).

mp: about 160 °C.

Chromatography. Thin-layer chromatography (*2.2.27*), using cellulose for chromatography f_{254} R as the coating substance: apply to the plate 20 µL of a solution of the 2-iodobenzoic acid, prepared by dissolving 40 mg in 4 mL of *0.1 M sodium hydroxide* and diluting to 10 mL with *water R*. Develop over a path of about 12 cm using as the mobile phase the upper layer obtained by shaking together 20 volumes of *water R*, 40 volumes of *glacial acetic acid R* and 40 volumes of *toluene R*. Allow the plate to dry in air and examine in ultraviolet light at 254 nm. The chromatogram shows only one principal spot.

3-Iodobenzylammonium chloride. C_7H_9ClIN. (M_r 269.5). *1168000.* [3718-88-5]. 1-(3-Iodophenyl)methanamine hydrochloride. 1-(3-Iodophenyl)methanaminium chloride. *m*-Iodobenzylamine hydrochloride.

White or almost white crystals.

mp: 188 °C to 190 °C.

Iodoethane. C_2H_5I. (M_r 155.9). *1099100.* [75-03-6].

Colourless or slightly yellowish liquid, darkening on exposure to air and light, miscible with ethanol (96 per cent) and most organic solvents.

d_{20}^{20}: about 1.95.

n_D^{20}: about 1.513.

bp: about 72 °C.

Storage: in an airtight container.

2-Iodohippuric acid. $C_9H_8INO_3,2H_2O$. (M_r 341.1). *1046200.* [147-58-0]. 2-(2-Iodobenzamido)acetic acid.

White or almost white, crystalline powder, sparingly soluble in water.

mp: about 170 °C.

Water (*2.5.12*): 9 per cent to 13 per cent, determined on 1.000 g.

Chromatography. Thin-layer chromatography (*2.2.27*), using *cellulose for chromatography F_{254} R* as the coating substance: apply to the plate 20 µL of a solution of the 2-iodohippuric acid, prepared by dissolving 40 mg in 4 mL of *0.1 M sodium hydroxide* and diluting to 10 mL with *water R*. Develop over a path of about 12 cm using as the mobile phase the upper layer obtained by shaking together 20 volumes of *water R*, 40 volumes of *glacial acetic acid R* and 40 volumes of *toluene R*. Allow the plate to dry in air and examine in ultraviolet light at 254 nm. The chromatogram shows only one principal spot.

Iodoplatinate reagent. *1046300.*

To 3 mL of a 100 g/L solution of *chloroplatinic acid R* add 97 mL of *water R* and 100 mL of a 60 g/L solution of *potassium iodide R*.

Storage: protected from light.

Iodoplatinate reagent R1. *1172200.*

Mix 2.5 mL of a 50 g/L solution of *chloroplatinic acid R*, 22.5 mL of a 100 g/L solution of *potassium iodide R* and 50 mL of *water R*.

Storage: protected from light, at a temperature of 2-8 °C.

Iodosulfurous reagent. *1046400.*

The apparatus, which must be kept closed and dry during the preparation, consists of a 3000 mL to 4000 mL round-bottomed flask with three inlets for a stirrer and a thermometer and fitted with a drying tube. To 700 mL of *anhydrous pyridine R* and 700 mL of *ethyleneglycol monomethyl ether R* add, with constant stirring, 220 g of finely powdered *iodine R*, previously dried over *diphosphorus pentoxide R*. Continue stirring until the iodine has completely dissolved (about 30 min). Cool to – 10 °C, and add quickly, still stirring, 190 g of *sulfur dioxide R*. Do not allow the temperature to exceed 30 °C. Cool.

Assay. Add about 20 mL of *anhydrous methanol R* to a titration vessel and titrate to the end-point with the iodosulfurous reagent (*2.5.12*). Introduce in an appropriate form a suitable amount of *water R*, accurately weighed, and repeat the determination of water. Calculate the water equivalent in milligrams per millilitre of iodosulfurous reagent.

The minimum water equivalent is 3.5 mg of water per millilitre of reagent.

Work protected from humidity. Standardise immediately before use.

Storage: in a dry container.

5-Iodouracil. $C_4H_3IN_2O_2$. (M_r 238.0). *1046500.* [696-07-1]. 5-Iodo-1*H*,3*H*-pyrimidine-2,4-dione.

mp: about 276 °C, with decomposition.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Idoxuridine (0669)*: apply 5 µL of a 0.25 g/L solution; the chromatogram obtained shows only one principal spot.

Ion-exclusion resin for chromatography. *1131000.*

A resin with sulfonic acid groups attached to a polymer lattice consisting of polystyrene cross-linked with divinylbenzene.

Ion-exchange resin, strongly acidic. *1085400.*

Resin in protonated form with sulfonic acid groups attached to a lattice consisting of polystyrene cross-linked with 8 per cent of divinylbenzene. It is available as spherical beads; unless otherwise prescribed, the particle size is 0.3 mm to 1.2 mm.

Capacity. 4.5 mmol to 5 mmol per gram, with a water content of 50 per cent to 60 per cent.

Preparation of a column. Unless otherwise prescribed, use a tube with a fused-in sintered glass disc having a length of 400 mm, an internal diameter of 20 mm and a filling height of about 200 mm. Introduce the resin, mixing it with *water R* and pouring the slurry into the tube, ensuring that no air bubbles are trapped between the particles. When in use, the liquid must not be allowed to fall below the surface of the resin. If the resin is in its protonated form, wash with *water R* until 50 mL requires not more than 0.05 mL of *0.1 M sodium hydroxide* for neutralisation, using 0.1 mL of *methyl orange solution R* as indicator.

If the resin is in its sodium form or if it requires regeneration, pass about 100 mL of a mixture of equal volumes of *hydrochloric acid R1* and *water R* slowly through the column and then wash with *water R* as described above.

Iron. Fe. (A_r 55.85). *1046600.* [7439-89-6].

Grey powder or wire, soluble in dilute mineral acids.

Iron salicylate solution. *1046700.*

Dissolve 0.1 g of *ferric ammonium sulfate R* in a mixture of 2 mL of *dilute sulfuric acid R* and 48 mL of *water R* and dilute to 100 mL with *water R*. Add 50 mL of a 11.5 g/L solution of *sodium salicylate R*, 10 mL of *dilute acetic acid R*, 80 mL of a 136 g/L solution of *sodium acetate R* and dilute to 500 mL with *water R*. The solution should be recently prepared.

Storage: in an airtight container, protected from light.

Isatin. $C_8H_5NO_2$. (M_r 147.1). *1046800.* [91-56-5]. Indoline-2,3-dione.

Small, yellowish-red crystals, slightly soluble in water, soluble in hot water and in ethanol (96 per cent), soluble in solutions of alkali hydroxides giving a violet colour becoming yellow on standing.

mp: about 200 °C, with partial sublimation.

Sulfated ash (*2.4.14*): maximum 0.2 per cent.

Isatin reagent. *1046801.*

Dissolve 6 mg of *ferric sulfate R* in 8 mL of *water R* and add cautiously 50 mL of *sulfuric acid R*. Add 6 mg of *isatin R* and stir until dissolved.

The reagent should be pale yellow, but not orange or red.

Isoamyl alcohol. $C_5H_{12}O$. (M_r 88.1). *1046900.* [123-51-3]. 3-Methylbutan-1-ol.

Colourless liquid, slightly soluble in water, miscible with ethanol (96 per cent).

bp: about 130 °C.

Isoamyl benzoate. $C_{12}H_{16}O_2$. (M_r 192.3). *1164200.* [94-46-2]. Isopentyl benzoate. 3-Methylbutyl benzoate.

n_D^{20}: about 1.494.

bp: about 261 °C.

Colourless or pale yellow liquid.

Isoandrosterone. $C_{19}H_{30}O_2$. (M_r 290.4). *1107100.* [481-29-8]. Epiandrosterone. 3β-Hydroxy-5α-androstan-17-one.

White or almost white powder, practically insoluble in water, soluble in organic solvents.

$[\alpha]_D^{20}$: + 88, determined on 20 g/L solution in *methanol R*.

mp: 172 °C to 174 °C.

ΔA (*2.2.41*): 14.24×10^3, determined at 304 nm on a 1.25 g/L solution.

***N*-Isobutyldodecatetraenamide.** $C_{16}H_{25}NO$. (M_r 247.4). *1159500.* [75917-90-7]. (2*E*,4*E*,8*Z*,10*EZ*)-*N*-2-(Methylpropyl)dodeca-2,4,8,10-tetraenamide.

White or almost white to non coloured crystals.

mp: about 70 °C.

***N*-Isobutyldodecatetraenamide solution.** *1159501.*

A solution of *N-isobutyldodecatetraenamide R*, exactly weighed, in *methanol R* at a concentration of about 10 mg/mL.

Isodrin. $C_{12}H_8Cl_6$. (M_r 364.9). *1128700.* [465-73-6]. 1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-*endo*,*endo*-1,4:5,8-dimethanonaphthalene.

Practically insoluble in water, soluble in common organic solvents such as acetone.

A suitable certified reference solution may be used.

Isomalt. $C_{12}H_{24}O_{11}$. (M_r 344.3). *1164300.* [64519-82-0].

Mixture of 6-*O*-α-D-glucopyranosyl-D-glucitol and of 1-*O*-α-D-glucopyranosyl-D-mannitol.

White or almost white powder or granules, freely soluble in water.

Isomaltitol. $C_{12}H_{24}O_{11}$. (M_r 344.3). *1161200.* [534-73-6]. 6-*O*-α-D-Glucopyranosyl-D-glucitol.

White or almost white powder, freely soluble in water.

Isomenthol. $C_{10}H_{20}O$. (M_r 156.3). *1047000.* [23283-97-8]. (+)-*Isomenthol:* (1*S*,2*R*,5*R*)-2-isopropyl-5-methylcyclohexanol. (±)-*Isomenthol:* a mixture of equal parts of (1*S*,2*R*,5*R*)- and (1*R*,2*S*,5*S*)-2-isopropyl-5-methylcyclohexanol.

Colourless crystals, practically insoluble in water, very soluble in ethanol (96 per cent).

$[\alpha]_D^{20}$: (+)-*Isomenthol*: about + 24, determined on a 100 g/L solution in *ethanol (96 per cent) R*.

bp: (+)-*Isomenthol*: about 218 °C. (±)-*Isomenthol*: about 218 °C.

mp: (+)-*Isomenthol*: about 80 °C. (±)-*Isomenthol*: about 53 °C.

(+)-Isomenthone. $C_{10}H_{18}O$. (M_r 154.2). *1047100.* (1*R*)-*cis*-*p*-Menthan-3-one. (1*R*)-*cis*-2-Isopropyl-5-methylcyclohexanone.

Contains variable amounts of menthone. A colourless liquid, very slightly soluble in water, soluble in ethanol (96 per cent).

d_{20}^{20}: about 0.904.

n_D^{20}: about 1.453.

$[\alpha]_D^{20}$: about + 93.2.

Isomenthone used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*

Test solution. The substance to be examined.

Content: minimum 80.0 per cent, calculated by the normalisation procedure.

Isopropylamine. C_3H_9N. (M_r 59.1). *1119800.* [75-31-0]. Propan-2-amine.

Colourless, highly volatile, flammable liquid.

n_D^{20}: about 1.374.

bp: 32 °C to 34 °C.

Isopropyl iodide. C_3H_7I. (M_r 170.0). *1166600.* [75-30-9]. 2-Iodopropane.

Isopropyl myristate. *1047200.* [110-27-0].

See *Isopropyl myristate (0725).*

4-Isopropylphenol. $C_9H_{12}O$. (M_r 136.2). *1047300.* [99-89-8].

Content: minimum 98 per cent.

bp: about 212 °C.

mp: 59 °C to 61 °C.

Isopulegol. $C_{10}H_{18}O$. (M_r 154.2). *1139600.* [89-79-2]. (–)-Isopulegol. (1*R*,2*S*,5*R*)-2-Isopropenyl-5-methylcyclohexanol.

d_4^{20}: about 0.911.

n_D^{20}: about 1.472.

bp: about 91 °C.

Isopulegol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Mint oil, partly dementholised (1838).*

Content: minimum 99 per cent, calculated by the normalisation procedure.

Isoquercitroside. $C_{21}H_{20}O_{12}$. (M_r 464.4). *1136500.* [21637-25-2]. Isoquercitrin. 2-(3,4-Dihydroxyphenyl)-3-(β-D-glucofuranosyloxy)-5,7-dihydroxy-4*H*-1-benzopyran-4-one. 3,3′,4′,5,7-Pentahydroxyflavone-3-glucoside.

Isosilibinin. $C_{25}H_{22}O_{10}$. (M_r 482.4). *1149900.* [72581-71-6]. 3,5,7-Trihydroxy-2-[2-(4-hydroxy-3-methoxyphenyl)-3-hydroxymethyl-2,3-dihydro-1,4-benzodioxin-6-yl]chroman-4-one.

White to yellowish powder, practically insoluble in water, soluble in acetone and in methanol.

Kaolin, light. *1047400.* [1332-58-7].

A purified native hydrated aluminium silicate. It contains a suitable dispersing agent.

Light, white or almost white powder free from gritty particles, unctuous to the touch, practically insoluble in water and in mineral acids.

Coarse particles: maximum 0.5 per cent.

Place 5.0 g in a ground-glass-stoppered cylinder about 160 mm long and 35 mm in diameter and add 60 mL of a 10 g/L solution of *sodium pyrophosphate R*. Shake vigorously and allow to stand for 5 min. Using a pipette, remove 50 mL of the liquid from a point about 5 cm below the surface. To the remaining liquid add 50 mL of *water R*, shake, allow to stand for 5 min and remove 50 mL as before. Repeat the operations until a total of 400 mL has been removed. Transfer the remaining suspension to an evaporating dish. Evaporate to dryness on a water-bath and dry the residue to constant mass at 100-105 °C. The residue weighs not more than 25 mg.

Fine particles. Disperse 5.0 g in 250 mL of *water R* by shaking vigorously for 2 min. Immediately pour into a glass cylinder 50 mm in diameter and, using a pipette, transfer 20 mL to a glass dish, evaporate to dryness on a water-bath and dry to constant mass at 100-105 °C. Allow the remainder of the suspension to stand at 20 °C for 4 h and, using a pipette with its tip exactly 5 cm below the surface, withdraw a further 20 mL without disturbing the sediment, place in a glass dish, evaporate to dryness on a water-bath and dry to constant mass at 100-105 °C. The mass of the second residue is not less than 70 per cent of that of the first residue.

11-Keto-β-boswellic acid. $C_{30}H_{46}O_4$. (M_r 470.7). *1167600.* [17019-92-0]. 3α-Hydroxy-11-oxours-12-en-24-oic acid. (4β)-3α-Hydroxy-11-oxours-12-en-23-oic acid.

White or almost white powder, insoluble in water, soluble in acetone, in anhydrous ethanol and in methanol.

mp: 195 °C to 197 °C.

11-Keto-β-boswellic acid used in liquid chromatography complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Indian frankincense (2310).*

Content: minimum 90 per cent, calculated by the normalisation procedure.

Kieselguhr for chromatography. *1047500.*

White or yellowish-white, light powder, practically insoluble in water, in dilute acids and in organic solvents.

Filtration rate. Use a chromatography column 0.25 m long and 10 mm in internal diameter with a sintered-glass (100) plate and two marks at 0.10 m and 0.20 m above the plate. Place sufficient of the substance to be examined in the column to reach the first mark and fill to the second mark with *water R*. When the first drops begin to flow from the column, fill to the second mark again with *water R* and measure the time required for the first 5 mL to flow from the column. The flow rate is not less than 1 mL/min.

Appearance of the eluate. The eluate obtained in the test for filtration rate is colourless (*Method I, 2.2.2*).

Acidity or alkalinity. To 1.00 g add 10 mL of *water R*, shake vigorously and allow to stand for 5 min. Filter the suspension on a filter previously washed with hot *water R* until the washings are neutral. To 2.0 mL of the filtrate add 0.05 mL of *methyl red solution R*; the solution is yellow. To 2.0 mL of the filtrate add 0.05 mL of *phenolphthalein solution R1*; the solution is at most slightly pink.

Water-soluble substances. Place 10.0 g in a chromatography column 0.25 m long and 10 mm in internal diameter and elute with *water R*. Collect the first 20 mL of eluate, evaporate to dryness and dry the residue at 100 °C to 105 °C. The residue weighs not more than 10 mg.

Iron (*2.4.9*): maximum 200 ppm.

To 0.50 g add 10 mL of a mixture of equal volumes of *hydrochloric acid R1* and *water R*, shake vigorously, allow to stand for 5 min and filter. 1.0 mL of the filtrate complies with the test for iron.

Loss on ignition: maximum 0.5 per cent. During heating to red heat (600 ± 50 °C) the substance does not become brown or black.

Kieselguhr G. *1047600.*

Consists of kieselguhr treated with hydrochloric acid and calcined, to which is added about 15 per cent of calcium sulfate hemihydrate.

A fine greyish-white powder; the grey colour becomes more pronounced on triturating with water. The average particle size is 10-40 µm.

Calcium sulfate content. Determine by the method prescribed for *silica gel G R*.

pH (*2.2.3*). Shake 1 g with 10 mL of *carbon dioxide-free water R* for 5 min. The pH of the suspension is 7 to 8.

Chromatographic separation. Thin-layer chromatography (*2.2.27*). Prepare plates using a slurry of the kieselguhr G with a 2.7 g/L solution of *sodium acetate R*. Apply 5 µL of a solution containing 0.1 g/L of lactose, sucrose, glucose and fructose in *pyridine R*. Develop over a path of 14 cm using a mixture of 12 volumes of *water R*, 23 volumes of *2-propanol R* and 65 volumes of *ethyl acetate R*. The migration time of the solvent is about 40 min. Dry, spray onto the plate about 10 mL of *anisaldehyde solution R* and heat for 5-10 min at 100-105 °C. The chromatogram shows four well-defined spots without tailing and well separated from each other.

Lactic acid. *1047800.* [50-21-5].

See *Lactic acid (0458).*

Lactic reagent. *1047801.*

Solution A. To 60 mL of *lactic acid R* add 45 mL of previously filtered *lactic acid R* saturated without heating with *Sudan red G R*; as lactic acid saturates slowly without heating, an excess of colorant is always necessary.

Solution B. Prepare 10 mL of a saturated solution of *aniline R*. Filter.

Solution C. Dissolve 75 mg of *potassium iodide R* in water and dilute to 70 mL with the same solvent. Add 10 mL of *ethanol (96 per cent) R* and 0.1 g of *iodine R*. Shake.

Mix solutions A and B. Add solution C.

Lactobionic acid. $C_{12}H_{22}O_{12}$. (M_r 358.3). *1101600.* [96-82-2].

White or almost white, crystalline powder, freely soluble in water, practically insoluble in ethanol (96 per cent).

mp: about 115 °C.

Lactose. *1047900.* [5989-81-1].

See *Lactose (0187).*

β-Lactose. $C_{12}H_{22}O_{11}$. (M_r 342.3). *1150100.* [5965-66-2]. β-D-Lactose.

White or slightly yellowish powder.

Content: minimum 99 per cent.

α-D-Lactose: not greater than 35 per cent.

Assay. Gas chromatography (*2.2.28*): use the normalisation procedure.

Column:

– *size*: *l* = 30 m, Ø = 0.25 mm;
– *stationary phase*: *poly[(cyanopropyl)(phenyl)][dimethyl] siloxane R* (film thickness 1 µm).

Carrier gas: *helium for chromatography R.*

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 32.5	20 → 280
Injection port		250
Detector		250

Detection: flame ionisation.

Injection: an appropriate derivatised sample.

α-Lactose monohydrate. $C_{12}H_{22}O_{11},H_2O$. (M_r 360.3). *1150000.* [5989-81-1]. α-D-Lactose monohydrate.

White or almost white powder.

Content: minimum 97 per cent.

β-D-Lactose: less than 3 per cent.

Assay. Gas chromatography (*2.2.28*): use the normalisation procedure.

Column:

– *size*: *l* = 30 m, Ø = 0.25 mm;
– *stationary phase*: *poly(dimethyl)siloxane R* (film thickness 1 µm).

Carrier gas: *helium for chromatography R.*

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 12.5	230 → 280
Injection port		250
Detector		280

Detection: flame ionisation.

Injection: an appropriate derivatised sample.

Lanatoside C. $C_{49}H_{76}O_2$. (M_r 985). *1163300.* [17575-22-3]. 3β-[(β-D-Glucopyranosyl-(1→4)-3-*O*-acetyl-2,6-dideoxy-β-D-*ribo*-hexopyranosyl-(1→4)-2,6-dideoxy-β-D-*ribo*-hexopyranosyl-(1→4)-2,6-dideoxy-β-D-*ribo*-hexopyranosyl)oxy]-12β,14-dihydroxy-5β-card-20(22)-enolide.

Long flat prisms obtained after recrystallisation in ethanol (96 per cent).

Freely soluble in pyridine and in dioxane.

Lanthanum chloride heptahydrate. $LaCl_3,7H_2O$. (M_r 371.4). *1167200.*

White or almost white powder or colourless crystals, freely soluble in water.

Lanthanum nitrate. $La(NO_3)_3,6H_2O$. (M_r 433.0). *1048000.* [10277-43-7]. Lanthanum trinitrate hexahydrate.

Colourless crystals, deliquescent, freely soluble in water.

Storage: in an airtight container.

Lanthanum nitrate solution. *1048001.*

A 50 g/L solution.

Lanthanum trioxide. La_2O_3. (M_r 325.8). *1114000.* [1312-81-8].

An almost white, amorphous powder, practically insoluble in *water R*. It dissolves in dilute solutions of mineral acids and absorbs atmospheric carbon dioxide.

Calcium: maximum 5 ppm.

Lanthanum chloride solution. *1114001.*

To 58.65 g of *lanthanum trioxide R* slowly add 100 mL of *hydrochloric acid R*. Heat to boiling. Allow to cool and dilute to 1000.0 mL with *water R*.

Lauric acid. $C_{12}H_{24}O_2$. (M_r 200.3). *1143100.* [143-07-7]. Dodecanoic acid.

White or almost white, crystalline powder, practically insoluble in water, freely soluble in ethanol (96 per cent).

mp: about 44 °C.

Lauric acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

Lauryl alcohol. $C_{12}H_{26}O$. (M_r 186.3). *1119900.* [112-53-8]. Dodecan-1-ol.

d_{20}^{20}: about 0.820.

mp: 24 °C to 27 °C.

Content: minimum 98.0 per cent, determined by gas chromatography.

Lavandulol. $C_{10}H_{18}O$. (M_r 154.2). *1114100.* [498-16-8]. (*R*)-5-Methyl-2-(1-methylethenyl)-4-hexen-1-ol.

Oily liquid with a characteristic odour.

Lavandulol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Lavender oil (1338).*

Test solution. The substance to be examined.

Content: minimum 90.0 per cent, calculated by the normalisation procedure.

Lavandulyl acetate. $C_{12}H_{20}O_2$. (M_r 196.3). *1114200.* [25905-14-0]. 2-Isopropenyl-5-methylhex-4-en-1-yl acetate.

Colourless liquid with a characteristic odour.

Lavandulyl acetate used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Lavender oil (1338).*

Test solution. The substance to be examined.

Content: minimum 93.0 per cent, calculated by the normalisation procedure.

Lead acetate. $C_4H_6O_4Pb,3H_2O$. (M_r 379.3). *1048100.* [6080-56-4]. Lead di-acetate.

Colourless crystals, efflorescent, freely soluble in water, soluble in ethanol (96 per cent).

Lead acetate cotton. *1048101.*

Immerse absorbent cotton in a mixture of 1 volume of *dilute acetic acid R* and 10 volumes of *lead acetate solution R*. Drain off the excess of liquid, without squeezing the cotton, by placing it on several layers of filter paper. Allow to dry in air.

Storage: in an airtight container.

Lead acetate paper. *1048102.*

Immerse filter paper weighing about 80 g/m² in a mixture of 1 volume of *dilute acetic acid R* and 10 volumes of *lead acetate solution R*. After drying, cut the paper into strips 15 mm by 40 mm.

Lead acetate solution. *1048103.*

A 95 g/L solution in *carbon dioxide-free water R*.

Lead dioxide. PbO_2. (M_r 239.2). *1048200.* [1309-60-0].

Dark brown powder, evolving oxygen when heated, practically insoluble in water, soluble in hydrochloric acid with evolution of chlorine, soluble in dilute nitric acid in the presence of hydrogen peroxide, oxalic acid or other reducing agents, soluble in hot, concentrated alkali hydroxide solutions.

Lead nitrate. $Pb(NO_3)_2$. (M_r 331.2). *1048300.* [10099-74-8]. Lead dinitrate.

White or almost white, crystalline powder or colourless crystals, freely soluble in water.

Lead nitrate solution. *1048301.*

A 33 g/L solution.

Lead subacetate solution. *1048400.* [1335-32-6]. Basic lead acetate solution.

Content: 16.7 per cent *m/m* to 17.4 per cent *m/m* of Pb (A_r 207.2) in a form corresponding approximately to the formula $C_8H_{14}O_{10}Pb_3$.

Dissolve 40.0 g of *lead acetate R* in 90 mL of *carbon dioxide-free water R*. Adjust the pH to 7.5 with *strong sodium hydroxide solution R*. Centrifuge and use the clear colourless supernatant solution.

The solution remains clear when stored in a well-closed container.

Leiocarposide. $C_{27}H_{34}O_{16}$. (M_r 614.5). *1150200.* [71953-77-0]. 2-(β-D-Glucopyranosyloxy)benzyl 3-(β-D-glucopyranosyloxy)-6-hydroxy-2-methoxybenzoate. 2-[[[3-(β-D-Glucopyranosyloxy)-6-hydroxy-2-methoxybenzoyl]oxy]methyl]phenyl-β-D-glucopyranoside.

White or almost white powder, soluble in water, freely soluble in methanol, slightly soluble in ethanol (96 per cent).

mp: 190 °C to 193 °C.

Lemon oil. *1101700.*

See *Lemon oil (0620).*

Leucine. *1048500.* [61-90-5].

See *Leucine (0771).*

Levodopa. *1170000.* [59-92-7].

See *Levodopa (0038).*

Limonene. $C_{10}H_{16}$. (M_r 136.2). *1048600.* [5989-27-5]. D-Limonene. (+)-*p*-Mentha-1,8-diene. (*R*)-4-Isopropenyl-1-methylcyclohex-1-ene.

Colourless liquid, practically insoluble in water, soluble in ethanol (96 per cent).

d_{20}^{20}: about 0.84.

n_D^{20}: 1.471 to 1.474.

$[\alpha]_D^{20}$: about + 124.

bp: 175 °C to 177 °C.

Limonene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*

Test solution. The substance to be examined.

Content: minimum 99.0 per cent, calculated by the normalisation procedure.

Linalol. $C_{10}H_{18}O$. (M_r 154.2). *1048700.* [78-70-6]. (*RS*)-3,7-Dimethylocta-1,6-dien-3-ol.

Mixture of two stereoisomers (licareol and coriandrol).

Liquid, practically insoluble in water.

d_{20}^{20}: about 0.860.

n_D^{20}: about 1.462.

bp: about 200 °C.

Linalol used in gas chromatography complies with the following test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Anise oil (0804).*

Test solution. The substance to be examined.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Linalyl acetate. $C_{12}H_{20}O_2$. (M_r 196.3). *1107200.* [115-95-7]. (*RS*)-1,5-Dimethyl-1-vinylhex-4-enyl acetate.

Colourless or slightly yellow liquid with a strong odour of bergamot and lavender.

d_{25}^{25}: 0.895 to 0.912.

n_D^{20}: 1.448 to 1.451.

bp: about 215 °C.

Linalyl acetate used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Bitter-orange-flower oil (1175).*

Test solution. The substance to be examined.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Lindane. $C_6H_6Cl_6$. (M_r 290.8). *1128900.* [58-89-9]. γ-Hexachlorocyclohexane.

For the monograph *Wool fat (0134)*, a suitable certified reference solution (10 ng/µL in cyclohexane) may be used.

Linoleic acid. $C_{18}H_{32}O_2$. (M_r 280.5). *1143200.* [60-33-3]. (9*Z*,12*Z*)-Octadeca-9,12-dienoic acid.

Colourless, oily liquid.

d_4^{20}: about 0.903.

n_D^{20}: about 1.470.

Linoleic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

Linolenic acid. $C_{18}H_{30}O_2$. (M_r 278.4). *1143300.* [463-40-1]. (9*Z*,12*Z*,15*Z*)-Octadeca-9,12,15-trienoic acid.

Colourless liquid, practically insoluble in water, soluble in organic solvents.

d_4^{20}: about 0.915.

n_D^{20}: about 1.480.

Linolenic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

Linolenyl alcohol. $C_{18}H_{32}O$. (M_r 264.4). *1156200.* [24149-05-1]. (9*Z*,12*Z*,15*Z*)-octadeca-9,12,15-trien-1-ol.

Content: minimum 96 per cent.

Linoleyl alcohol. $C_{18}H_{34}O$. (M_r 266.5). *1155900.* [506-43-4]. (9*Z*,12*Z*)-octadeca-9,12-dien-1-ol.

Relative density: 0.830.

Content: minimum 85 per cent.

Linsidomine hydrochloride. $C_6H_{11}ClN_4O_2$. (M_r 206.6). *1171200.* [16142-27-1]. 3-(Morpholin-4-yl)sydnonimine hydrochloride. 3-(Morpholin-4-yl)-1,2,3-oxadiazol-3-ium-5-aminide hydrochloride.

White or almost white powder.

Liquid scintillation cocktail. *1167300.*

Commercially available solution for the determination of radioactivity by liquid scintillation counting. It contains one or more fluorescent agents and mostly one or more emulsifying agents in a suitable organic solvent or mixture of organic solvents.

Liquid scintillation cocktail R1. *1176800.*

To 1000 mL of *dioxan R*, add 0.3 g of *methylphenyloxazolylbenzene R*, 7 g of *diphenyloxazole R* and 100 g of *naphthalene R*.

Lithium. Li. (A_r 6.94). *1048800.* [7439-93-2].

A soft metal whose freshly cut surface is silvery-grey. It rapidly tarnishes in contact with air. It reacts violently with water, yielding hydrogen and giving a solution of lithium hydroxide; soluble in methanol, yielding hydrogen and a solution of lithium methoxide; practically insoluble in light petroleum.

Storage: under light petroleum or liquid paraffin.

Lithium carbonate. Li_2CO_3. (M_r 73.9). *1048900.* [554-13-2]. Dilithium carbonate.

White or almost white, light powder, sparingly soluble in water, very slightly soluble in ethanol (96 per cent). A saturated solution at 20 °C contains about 13 g/L of Li_2CO_3.

Lithium chloride. LiCl. (M_r 42.39). *1049000.* [7447-41-8].

Crystalline powder or granules or cubic crystals, deliquescent, freely soluble in water, soluble in acetone and in ethanol (96 per cent). Aqueous solutions are neutral or slightly alkaline.

Storage: in an airtight container.

Lithium hydroxide. $LiOH,H_2O$. (M_r 41.96). *1049100.* [1310-66-3]. Lithium hydroxide monohydrate.

White or almost white, granular powder, strongly alkaline, it rapidly absorbs water and carbon dioxide, soluble in water, sparingly soluble in ethanol (96 per cent).

Storage: in an airtight container.

Lithium metaborate, anhydrous. $LiBO_2$. (M_r 49.75). *1120000.* [13453-69-5].

Lithium sulfate. Li_2SO_4,H_2O. (M_r 128.0). *1049200.* [10102-25-7]. Dilithium sulfate monohydrate.

Colourless crystals, freely soluble in water, practically insoluble in ethanol (96 per cent).

Lithium trifluoromethanesulfonate. CF_3LiO_3S. (M_r 156.0). *1173400.* [33454-82-9].

Litmus. *1049300.* [1393-92-6].

Schultz No. 1386.

Indigo-blue fragments prepared from various species of Rocella, Lecanora or other lichens, soluble in water, practically insoluble in ethanol (96 per cent).

Colour change: pH 5 (red) to pH 8 (blue).

Litmus paper, blue. *1049301.*

Boil 10 parts of coarsely powdered *litmus R* for 1 h with 100 parts of *ethanol (96 per cent) R*. Decant the alcohol and add to the residue a mixture of 45 parts of *ethanol (96 per cent) R* and 55 parts of *water R*. After 2 days decant the clear liquid. Impregnate strips of filter paper with the solution and allow to dry.

Test for sensitivity. Immerse a strip measuring 10 mm by 60 mm in a mixture of 10 mL of *0.02 M hydrochloric acid* and 90 mL of *water R*. On shaking the paper turns red within 45 s.

Litmus paper, red. *1049302.*

To the blue litmus extract, add *dilute hydrochloric acid R* dropwise until the blue colour becomes red. Impregnate strips of filter paper with the solution and allow to dry.

Test for sensitivity. Immerse a strip measuring 10 mm by 60 mm in a mixture of 10 mL of *0.02 M sodium hydroxide* and 90 mL of *water R*. On shaking the paper turns blue within 45 s.

Loganin. $C_{17}H_{26}O_{10}$. (M_r 390.4). *1136700.* [18524-94-2]. Methyl (1*S*,4a*S*,6*S*,7*R*,7a*S*)-1-(β-D-glucopyranosyloxy)-6-hydroxy-7-methyl-1,4a,5,6,7,7a-hexahydrocyclopenta[*c*]pyran-4-carboxylate.

mp: 220 °C to 221 °C.

Longifolene. $C_{15}H_{24}$. (M_r 204.4). *1150300.* [475-20-7]. (1*S*,3a*R*,4*S*,8a*S*)-4,8,8-Trimethyl-9-methylenedecahydro-1,4-methanoazulene.

Oily, colourless liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_4^{18}: 0.9319.

n_D^{20}: 1.5050.

$[\alpha]_D^{20}$: + 42.7.

bp: 254 °C to 256 °C.

Longifolene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Turpentine oil, Pinus pinaster type (1627).*

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Low-vapour-pressure hydrocarbons (type L). *1049400.*

Unctuous mass, soluble in benzene and in toluene.

Lumiflavine. $C_{13}H_{12}N_4O_2$. (M_r 256.3). *1141000.* [1088-56-8]. 7,8,10-Trimethylbenzo[*g*]pteridine-2,4(3*H*,10*H*)-dione.

Yellow powder or orange crystals, very slightly soluble in water, freely soluble in methylene chloride.

Luteolin-7-glucoside. $C_{21}H_{20}O_{11}$. (M_r 448.4). *1163400.* [5373-11-5]. 2-(3,4-Dihydroxyphenyl)-7-(β-D-glucopyranosyloxy)-5-hydroxy-4*H*-1-benzopyran-4-one.

Yellow powder.

Absorbance (*2.2.25*). A solution in *methanol R* shows absorption maxima at 255 nm, 267 nm, 290 nm and 350 nm.

mp: about 247 °C.

Macrogol 23 lauryl ether. *1129000.*

See *Macrogol lauryl ether (1124)*, the number of moles of ethylene oxide reacted per mole of lauryl alcohol being 23 (nominal value).

Macrogol 200. *1099200.* [25322-68-3]. Polyethyleneglycol 200.

Clear, colourless or almost colourless viscous liquid, very soluble in acetone and in anhydrous ethanol, practically insoluble in fatty oils.

d_{20}^{20}: about 1.127.

n_D^{20}: about 1.450.

Macrogol 200 R1. *1099201.*

Introduce 500 mL of *macrogol 200 R* into a 1000 mL round bottom flask. Using a rotation evaporator remove any volatile components applying for 6 h a temperature of 60 °C and a vacuum with a pressure of 1.5-2.5 kPa.

Macrogol 300. *1067100.* [25322-68-3]. Polyethyleneglycol 300.

See *Macrogols (1444)*.

Macrogol 400. *1067200.* [25322-68-3]. Polyethyleneglycol 400.

See *Macrogols (1444)*.

Macrogol 1000. *1067300.* [25322-68-3]. Polyethyleneglycol 1000.

See *Macrogols (1444)*.

Macrogol 1500. *1067400.* [25322-68-3]. Polyethyleneglycol 1500.

See *Macrogols (1444)*.

Macrogol 20 000. *1067600.* Polyethyleneglycol 20 000.

See *Macrogols (1444)*.

Macrogol 20 000 2-nitroterephthalate. *1067601.* Polyethyleneglycol 20 000 2-nitroterephthalate.

Macrogol 20 000 R modified by treating with 2-nitroterephthalate acid.

A hard, white or almost white, waxy solid, soluble in acetone.

Magnesium. Mg. (A_r 24.30). *1049500.* [7439-95-4].

Silver-white ribbon, turnings or wire, or a grey powder.

Magnesium acetate. $C_4H_6MgO_4,4H_2O$. (M_r 214.5). *1049600.* [16674-78-5]. Magnesium diacetate tetrahydrate.

Colourless crystals, deliquescent, freely soluble in water and in ethanol (96 per cent).

Storage: in an airtight container.

Magnesium chloride. *1049700.* [7791-18-6].

See *Magnesium chloride hexahydrate (0402)*.

Magnesium nitrate. $Mg(NO_3)_2,6H_2O$. (M_r 256.4). *1049800.* [13446-18-9]. Magnesium nitrate hexahydrate.

Colourless, clear crystals, deliquescent, very soluble in water, freely soluble in ethanol (96 per cent).

Storage: in an airtight container.

Magnesium nitrate solution. *1049801.*

Dissolve 17.3 g of *magnesium nitrate R* in 5 mL of *water R* warming gently and add 80 mL of *ethanol (96 per cent) R*. Cool and dilute to 100.0 mL with the same solvent.

Magnesium nitrate solution R1. *1049802.*

Dissolve 20 g of *magnesium nitrate R* ($Mg(NO_3)_2,6H_2O$) in *deionised distilled water R* and dilute to 100 mL with the same solvent. Immediately before use, dilute 10 mL to 100 mL with *deionised distilled water R*. A volume of 5 µL will provide 0.06 mg of Mg ($NO_3)_2$.

Magnesium oxide. *1049900.* [1309-48-4].

See *Light magnesium oxide (0040)*.

Magnesium oxide R1. *1049901.*

Complies with the requirements prescribed for *magnesium oxide R* with the following modifications.

Arsenic (*2.4.2, Method A*): maximum 2 ppm.

Dissolve 0.5 g in a mixture of 5 mL of *water R* and 5 mL of *hydrochloric acid R1*.

Heavy metals (*2.4.8*): maximum 10 ppm.

Dissolve 1.0 g in a mixture of 3 mL of *water R* and 7 mL of *hydrochloric acid R1*. Add 0.05 mL of *phenolphthalein solution R* and *concentrated ammonia R* until a pink colour is obtained. Neutralise the excess of ammonia by the addition of *glacial acetic acid R*. Add 0.5 mL in excess and dilute to 20 mL with *water R*. Filter, if necessary. 12 mL of the solution complies with test A. Prepare the reference solution using a mixture of 5 mL of *lead standard solution (1 ppm Pb) R* and 5 mL of *water R*.

Iron (*2.4.9*): maximum 50 ppm.

Dissolve 0.2 g in 6 mL of *dilute hydrochloric acid R* and dilute to 10 mL with *water R*.

Magnesium oxide, heavy. *1050000.* [1309-48-4].

See *Heavy magnesium oxide (0041)*.

Magnesium silicate for pesticide residue analysis. *1129100.* [1343-88-0].

Magnesium silicate for chromatography (60-100 mesh).

Magnesium sulfate. *1050200.* [10034-99-8].

See *Magnesium sulfate heptahydrate (0044)*.

Maize oil. *1050400.*

See *Maize oil, refined (1342)*.

Malachite green. $C_{23}H_{25}ClN_2$. (M_r 364.9). *1050500.* [123333-61-9].

Schultz No. 754.

Colour Index No. 42000.

[4-[[4-(Dimethylamino)phenyl]phenylmethylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride.

Green crystals with a metallic lustre, very soluble in water giving a bluish-green solution, soluble in ethanol (96 per cent) and in methanol.

Absorbance (*2.2.25*). A 0.01 g/L solution in *ethanol (96 per cent) R* shows an absorption maximum at 617 nm.

Malachite green solution. *1050501.*

A 5 g/L solution in *anhydrous acetic acid R*.

Malathion. $C_{10}H_{19}O_6PS_2$. (M_r 330.3). *1129200.* [121-75-5].

bp: about 156 °C.

A suitable certified reference solution (10 ng/µL in iso-octane) may be used.

Maleic acid. *1050600.* [110-16-7].
See *Maleic acid (0365).*

Maleic anhydride. $C_4H_2O_3$. (M_r 98.1). *1050700.* [108-31-6]. Butenedioic anhydride. 2,5-Furandione.
White or almost white crystals, soluble in water forming maleic acid, very soluble in acetone and in ethyl acetate, freely soluble in toluene, soluble in ethanol (96 per cent) with ester formation, very slightly soluble in light petroleum.
mp: about 52 °C.
Any residue insoluble in toluene does not exceed 5 per cent (maleic acid).

Maleic anhydride solution. *1050701.*
Dissolve 5 g of *maleic anhydride R* in *toluene R* and dilute to 100 mL with the same solvent. Use within one month. If the solution becomes turbid, filter.

Maltitol. *1136800.* [585-88-6].
See *Maltitol (1235).*

Maltotriose. $C_{18}H_{32}O_{16}$. (M_r 504.4). *1176300.* [1109-28-0]. α-D-Glucopyranosyl-(1→4)-α-D-glucopyranosyl-(1→4)-D-glucose.

Mandelic acid. $C_8H_8O_3$. (M_r 152.1). *1171300.* [90-64-2]. 2-Hydroxy-2-phenylacetic acid.
White crystalline flakes, soluble in water.
mp: 118 to 121 °C.

Manganese sulfate. $MnSO_4,H_2O$. (M_r 169.0). *1050900.* [10034-96-5]. Manganese sulfate monohydrate.
Pale-pink, crystalline powder or crystals, freely soluble in water, practically insoluble in ethanol (96 per cent).
Loss on ignition: 10.0 per cent to 12.0 per cent, determined on 1.000 g at 500 ± 50 °C.

Mannitol. *1051000.* [69-65-8].
See *Mannitol (0559).*

Mannose. $C_6H_{12}O_6$. (M_r 180.2). *1051100.* [3458-28-4]. D-(+)-Mannose.
white or almost white, crystalline powder or small crystals, very soluble in water, slightly soluble in anhydrous ethanol.
$[\alpha]_D^{20}$: + 13.7 + 14.7, determined on a 200 g/L solution in *water R* containing about 0.05 per cent of NH_3.
mp: about 132 °C, with decomposition.

Marrubiin. $C_{20}H_{28}O_4$. (M_r 332.4). *1158300.* [465-92-9]. (2a*S*,5a*S*,6*R*,7*R*,8a*R*,8b*R*)-6-[2-(Furan-3-yl)ethyl]-6-hydroxy-2a,5a,7-trimethyldecahydro-2*H*-naphtho[1,8-*bc*]furan-2-one.
Colourless, microcrystalline powder.
Marrubiin used in liquid chromatography complies with the following additional test.
Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *White horehound (1835).*
Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Meclozine dihydrochloride. *1051200.* [1104-22-9].
See *Meclozine dihydrochloride (0622).*

Melamine. $C_3H_6N_6$. (M_r 126.1). *1051300.* [108-78-1]. 1,3,5-Triazine-2,4,6-triamine.
A white or almost white, amorphous powder, very slightly soluble in water and in ethanol (96 per cent).

Menadione. *1051400.* [58-27-5].
See *Menadione (0507).*

Menthofuran. $C_{10}H_{14}O$. (M_r 150.2). *1051500.* [17957-94-7]. 3,9-Epoxy-*p*-mentha-3,8-diene. 3,6-Dimethyl-4,5,6,7-tetrahydrobenzofuran.
Slightly bluish liquid, very slightly soluble in water, soluble in ethanol (96 per cent).
d_{15}^{20}: about 0.965.
n_D^{20}: about 1.480.
$[\alpha]_D^{20}$: about + 93.
bp: 196 °C.
Menthofuran used in gas chromatography complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*
Test solution. The substance to be examined.
Content: minimum 97.0 per cent, calculated by the normalisation procedure.

Menthol. *1051600.* [2216-51-5].
See *Levomenthol (0619)* and *Racemic menthol (0623).*
Menthol used in gas chromatography complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the related substances test included in the monograph *Racemic menthol (0623).*
Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Menthone. $C_{10}H_{18}O$. (M_r 154.2). *1051700.* [14073-97-3]. (2*S*,5*R*)-2-Isopropyl-5-methylcyclohexanone. (−)-*trans*-*p*-Menthan-3-one.
Contains variable amounts of isomenthone.
Colourless liquid, very slightly soluble in water, very soluble in ethanol (96 per cent).
d_{20}^{20}: about 0.897.
n_D^{20}: about 1.450.
Menthone used in gas chromatography complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*
Test solution. The substance to be examined.
Content: minimum 90.0 per cent, calculated by the normalisation procedure.

Menthyl acetate. $C_{12}H_{22}O_2$. (M_r 198.3). *1051800.* [2623-23-6]. 2-Isopropyl-5-methylcyclohexyl acetate.
Colourless liquid, slightly soluble in water, miscible with ethanol (96 per cent).
d_{20}^{20}: about 0.92.
n_D^{20}: about 1.447.
bp: about 228 °C.
Menthyl acetate used in gas chromatography complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*
Test solution. The substance to be examined.
Content: minimum 97.0 per cent, calculated by the normalisation procedure.

2-Mercaptobenzimidazole. $C_7H_6N_2S$. (M_r 150.2). *1170100.* [583-39-1]. 1*H*-benzimidazole-2-thiol.
mp: about 302 °C.

2-Mercaptoethanol. C_2H_6OS. (M_r 78.1). *1099300.* [60-24-2].
Liquid, miscible with water.
d_{20}^{20}: about 1.116.
bp: about 157 °C.

Mercaptopurine. *1051900.* [6112-76-1].
See *Mercaptopurine (0096).*

Mercuric acetate. $C_4H_6HgO_4$. (M_r 318.7). *1052000.* [1600-27-7]. Mercury diacetate.
White or almost white crystals, freely soluble in water, soluble in ethanol (96 per cent).

Mercuric acetate solution. *1052001.*

Dissolve 3.19 g of *mercuric acetate R* in *anhydrous acetic acid R* and dilute to 100 mL with the same acid. If necessary, neutralise the solution with *0.1 M perchloric acid* using 0.05 mL of *crystal violet solution R* as indicator.

Mercuric bromide. $HgBr_2$. (M_r 360.4). *1052100.* [7789-47-1]. Mercury dibromide.

White or faintly yellow crystals or a crystalline powder, slightly soluble in water, soluble in ethanol (96 per cent).

Mercuric bromide paper. *1052101.*

In a rectangular dish place a 50 g/L solution of *mercuric bromide R* in *anhydrous ethanol R* and immerse in it pieces of white filter paper weighing 80 g per square metre (speed of filtration = filtration time expressed in seconds for 100 mL of water at 20 °C with a filter surface of 10 cm^2 and constant pressure of 6.7 kPa: 40 s to 60 s), each measuring 1.5 cm by 20 cm and folded in two. Allow the excess liquid to drain and allow the paper to dry, protected from light, suspended over a non-metallic thread. Discard 1 cm from each end of each strip and cut the remainder into 1.5 cm squares or discs of 1.5 cm diameter.

Storage: in a glass-stoppered container wrapped with black paper.

Mercuric chloride. *1052200.* [7487-94-7].

See *Mercuric chloride (0120)*.

Mercuric chloride solution. *1052201.*

A 54 g/L solution.

Mercuric iodide. HgI_2. (M_r 454.4). *1052300.* [7774-29-0]. Mercury di-iodide.

Dense, scarlet, crystalline powder, slightly soluble in water, sparingly soluble in acetone and in ethanol (96 per cent), soluble in an excess of *potassium iodide solution R*.

Storage: protected from light.

Mercuric nitrate. $Hg(NO_3)_2,H_2O$. (M_r 342.6). *1052400.* [7783-34-8]. Mercury dinitrate monohydrate.

Colourless or slightly coloured crystals, hygroscopic, soluble in water in the presence of a small quantity of nitric acid.

Storage: in an airtight container, protected from light.

Mercuric oxide. HgO. (M_r 216.6). *1052500.* [21908-53-2]. Yellow mercuric oxide. Mercury oxide.

A yellow to orange-yellow powder, practically insoluble in water and in ethanol (96 per cent).

Storage: protected from light.

Mercuric sulfate solution. *1052600.* [7783-35-9].

Dissolve 1 g of *mercuric oxide R* in a mixture of 20 mL of *water R* and 4 mL of *sulfuric acid R*.

Mercuric thiocyanate. $Hg(SCN)_2$. (M_r 316.7). *1052700.* [592-85-8]. Mercury di(thiocyanate).

White or almost white, crystalline powder, very slightly soluble in water, slightly soluble in ethanol (96 per cent), soluble in solutions of sodium chloride.

Mercuric thiocyanate solution. *1052701.*

Dissolve 0.3 g of *mercuric thiocyanate R* in *anhydrous ethanol R* and dilute to 100 mL with the same solvent.

Storage: use within 1 week.

Mercury. Hg. (A_r 200.6). *1052800.* [7439-97-6].

Silver-white liquid, breaking into spherical globules which do not leave a metallic trace when rubbed on paper.

d_{20}^{20}: about 13.5.

bp: about 357 °C.

Mercury, nitric acid solution of. *1052801.*

Carefully dissolve 3 mL of *mercury R* in 27 mL of *fuming nitric acid R*. Dilute the solution with an equal volume of *water R*.

Storage: protected from light; use within 2 months.

Mesityl oxide. $C_6H_{10}O$. (M_r 98.1). *1120100.* [141-79-7]. 4-Methylpent-3-en-2-one.

Colourless, oily liquid, soluble in 30 parts of water, miscible with most organic solvents.

d_{20}^{20}: about 0.858.

bp: 129 °C to 130 °C.

Metanil yellow. $C_{18}H_{14}N_3NaO_3S$. (M_r 375.4). *1052900.* [587-98-4].

Schultz No. 169.

Colour Index No. 13065.
Sodium 3-[4-(phenylamino)phenylazo]benzenesulfonate.

A brownish-yellow powder, soluble in water and in ethanol (96 per cent).

Metanil yellow solution. *1052901.*

A 1 g/L solution in *methanol R*.

Test for sensitivity. To 50 mL of *anhydrous acetic acid R* add 0.1 mL of the metanil yellow solution. Add 0.05 mL of *0.1 M perchloric acid*; the colour changes from pinkish-red to violet.

Colour change: pH 1.2 (red) to pH 2.3 (orange-yellow).

Metaphosphoric acid. $(HPO_3)_x$. *1053000.* [37267-86-0].

Glassy lumps or sticks containing a proportion of sodium metaphosphate, hygroscopic, very soluble in water.

Nitrates. Boil 1.0 g with 10 mL of *water R*, cool, add 1 mL of *indigo carmine solution R*, 10 mL of *nitrogen-free sulfuric acid R* and heat to boiling. The blue colour is not entirely discharged.

Reducing substances: maximum 0.01 per cent, calculated as H_3PO_3.

Dissolve 35.0 g in 50 mL of *water R*. Add 5 mL of a 200 g/L solution of *sulfuric acid R*, 50 mg of *potassium bromide R* and 5.0 mL of *0.02 M potassium bromate* and heat on a water-bath for 30 min. Allow to cool and add 0.5 g of *potassium iodide R*. Titrate the liberated iodine with *0.1 M sodium thiosulfate*, using 1 mL of *starch solution R* as indicator. Carry out a blank test.

1 mL of *0.02 M potassium bromate* is equivalent to 4.10 mg of H_3PO_3.

Storage: in an airtight container.

Methacrylic acid. $C_4H_6O_2$. (M_r 86.1). *1101800.* [79-41-4]. 2-Methylprop-2-enoic acid.

Colourless liquid.

n_D^{20}: about 1.431.

bp: about 160 °C.

mp: about 16 °C.

Methane. CH_4. (M_r 16). *1166300.* [74-82-8].

Content: minimum 99.0 per cent *V/V*.

Methane R1. CH_4. (M_r 16). *1176400.* [74-82-8].

Content: minimum 99.995 per cent *V/V*.

Methanesulfonic acid. CH_4O_3S. (M_r 96.1). *1053100.* [75-75-2].

Clear, colourless liquid, solidifying at about 20 °C, miscible with water, slightly soluble in toluene, practically insoluble in hexane.

d_{20}^{20}: about 1.48.

n_D^{20}: about 1.430.

Methanol. CH_4O. (M_r 32.04). *1053200.* [67-56-1].

Clear, colourless, flammable liquid, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: 0.791 to 0.793.

bp: 64 °C to 65 °C.

Methanol R1. *1053201.*

Complies with the requirements prescribed for *methanol R* and the following additional requirement.

Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 20 per cent at 210 nm, 50 per cent at 220 nm, 75 per cent at 230 nm, 95 per cent at 250 nm, 98 per cent at 260 nm and at higher wavelengths.

Methanol R2. *1053202.*

Complies with the requirements prescribed for *methanol R* and the following additional requirements.

Content: minimum 99.8 per cent.

Absorbance (2.2.25): maximum 0.17, determined at 225 nm using *water R* as the compensation liquid.

Methanol, hydrochloric. *1053203.*

Dilute 1.0 mL of *hydrochloric acid R1* to 100.0 mL with *methanol R*.

Methanol, aldehyde-free. *1053300.*

Dissolve 25 g of *iodine R* in 1 L of *methanol R* and pour the solution, with constant stirring, into 400 mL of *1 M sodium hydroxide*. Add 150 mL of *water R* and allow to stand for 16h. Filter. Boil under a reflux condenser until the odour of iodoform disappears. Distil the solution by fractional distillation.

Aldehydes and ketones: maximum 0.001 per cent.

Methanol, anhydrous. *1053400.* [67-56-1].

Treat 1000 mL of *methanol R* with 5 g of *magnesium R*. If necessary initiate the reaction by adding 0.1 mL of *mercuric chloride solution R*. When the evolution of gas has ceased, distil the liquid and collect the distillate in a dry container protected from moisture.

Water (*2.5.12*): maximum 0.3 g/L.

DL-Methionine. *1129400.* [59-51-8].

See *DL-Methionine (0624)*.

L-Methionine. *1053500.* [63-68-3].

See *Methionine (1027)*.

(*RS*)-Methotrexate. $C_{20}H_{22}N_8O_5$. *1120200.* [60388-6]. (*RS*)-2-[4-[[(2,4-diaminopteridin-6-yl)methyl]-methylamino]benzoylamino]pentanedioic acid.

Content: minimum 96.0 per cent.

mp: about 195 °C.

Methoxychlor. $C_{16}H_{15}Cl_3O_2$. (M_r 345.7). *1129300.* [72-43-5]. 1,1-(2,2,2-Trichloroethylidene)-bis(4-methoxybenzene).

Practically insoluble in water, freely soluble in most organic solvents.

bp: about 346 °C.

mp: 78 °C to 86 °C.

A suitable certified reference solution (10 ng/µL in iso-octane) may be used.

***trans*-2-Methoxycinnamaldehyde.** $C_{10}H_{10}O_2$. (M_r 162.2). *1129500.* [60125-24-8].

mp: 44 °C to 46 °C.

trans-2-Methoxycinnamaldehyde used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Cassia oil (1496)*.

Content: minimum 96.0 per cent, calculated by the normalisation procedure.

(1*RS*)-1-(6-Methoxynaphthalen-2-yl)ethanol. $C_{13}H_{14}O_2$. (M_r 202.3). *1159600.* [77301-42-9]. 6-Methoxy-α-methyl-2-naphthalenemethanol.

White or almost white powder.

mp: about 113 °C.

1-(6-Methoxynaphthalen-2-yl)ethanone. $C_{13}H_{12}O_2$. (M_r 200.2). *1159700.* [3900-45-6]. 6′-Methoxy-2′-acetonaphthone.

White or almost white powder.

mp: about 108 °C.

Methoxyphenylacetic acid. $C_9H_{10}O_3$. (M_r 166.2). *1053600.* [7021-09-2]. (*RS*)-2-Methoxy-2-phenylacetic acid.

White, crystalline powder or white or almost white crystals, sparingly soluble in water, freely soluble in ethanol (96 per cent).

mp: about 70 °C.

Methoxyphenylacetic reagent. *1053601.*

Dissolve 2.7 g of *methoxyphenylacetic acid R* in 6 mL of *tetramethylammonium hydroxide solution R* and add 20 mL of *anhydrous ethanol R*.

Storage: in a polyethylene container.

3-Methoxy-L-tyrosine. $C_{10}H_{13}NO_4H_2O$. (M_r 229.2). *1164400.* [200630-46-2].

Off-white or yellow powder.

Methyl acetate. $C_3H_6O_2$. (M_r 74.1). *1053700.* [79-20-9].

Clear, colourless liquid, soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.933.

n_D^{20}: about 1.361.

bp: 56 °C to 58 °C.

Methyl 4-acetylbenzoate. $C_{10}H_{10}O_3$. (M_r 178.2). *1154100.* [3609–8].

mp: about 94 °C.

Methyl 4-acetylbenzoate reagent. *1154101.*

Dissolve 0.25 g of *methyl 4-acetylbenzoate R* in a mixture of 5 mL of *sulfuric acid R* and 85 mL of cooled *methanol R*.

Methylal. $C_3H_8O_2$. (M_r 76.1). *1173500.* [109-87-5]. Dimethoxymethane. Dioxapentane. Formaldehyde dimethyl acetal. Methylene dimethyl ether.

Clear, colourless, volatile, flammable liquid, soluble in water and miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.860.

n_D^{20}: about 1.354.

bp: about 41 °C.

Methylal used in gas chromatography complies with the following additional test.

Content: minimum 99.5 per cent, determined by gas chromatography.

Methyl 4-aminobenzoate. $C_8H_9NO_2$. (M_r 151.2). *1175600.* [619-45-4].

mp: 110 °C to 113 °C.

4-Methylaminophenol sulfate. $C_{14}H_{20}N_2O_6S$. (M_r 344.4). *1053800.* [55-55-0].

Colourless crystals, very soluble in water, slightly soluble in ethanol (96 per cent).

mp: about 260 °C.

Methyl anthranilate. $C_8H_9NO_2$. (M_r 151.2). *1107300.* [134-20-3]. Methyl 2-aminobenzoate.

Colourless crystals or a colourless or yellowish liquid, soluble in water, freely soluble in ethanol (96 per cent).

bp: 134 °C to 136 °C.

mp: 24 °C to 25 °C.

Methyl anthranilate used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Bitter-orange-flower oil (1175).*

Test solution. The substance to be examined.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Methyl arachidate. $C_{21}H_{42}O_2$. (M_r 326.6). *1053900.* [1120-28-1]. Methyl eicosanoate.

Content: minimum 98.0 per cent, determined by gas chromatography (*2.4.22*).

White or yellow, crystalline mass, soluble in ethanol (96 per cent) and in light petroleum.

mp: about 46 °C.

Methyl behenate. $C_{23}H_{46}O_2$. (M_r 354.6). *1107500.* [929-77-1]. Methyl docosanoate.

mp: 54 °C to 55 °C.

Methyl benzenesulfonate. $C_7H_8O_3S$. (M_r 172.2). *1159800.* [80-18-2].

Clear, colourless liquid.

bp: about 148 °C.

Methyl benzoate. $C_8H_8O_2$. (M_r 136.2). *1164500.* [93-58-3]. Benzoic acid, methyl ester.

Colourless liquid.

d_4^{20}: 1.088.

bp: about 200 °C.

Methylbenzothiazolone hydrazone hydrochloride. $C_8H_{10}ClN_3S,H_2O$. (M_r 233.7). *1055300.* [38894-11-0]. 3-Methylbenzothiazol-2(3*H*)-one hydrazone hydrochloride monohydrate.

Almost white or yellowish, crystalline powder.

mp: about 270 °C.

Suitability for determination of aldehydes. To 2 mL of *aldehyde-free methanol R* add 60 µL of a 1 g/L solution of *propionaldehyde R* in *aldehyde-free methanol R* and 5 mL of a 4 g/L solution of methylbenzothiazolone hydrazone hydrochloride. Mix. Allow to stand for 30 min. Prepare a blank omitting the propionaldehyde solution. Add 25.0 mL of a 2 g/L solution of *ferric chloride R* to the test solution and to the blank, dilute to 100.0 mL with *acetone R* and mix. The absorbance (*2.2.25*) of the test solution, measured at 660 nm using the blank as compensation liquid, is not less than 0.62.

(*R*)-(+)-α-Methylbenzyl isocyanate. C_9H_9NO. (M_r 147.2). *1171400.* [33375-06-3]. (+)-(*R*)-α-Methylbenzyl isocyanate. (+)-[(1*R*)-1-Isocyanatoethyl]benzene. (+)-(1*R*)-1-Phenylethyl isocyanate.

Content: minimum 99.0 per cent.

Colourless liquid.

d_{20}^{20}: about 1.045.

n_D^{20}: about 1.513.

bp: 55 °C to 56 °C at 2.5 mm Hg.

Enantiomeric purity: minimum 99.5.

Storage: at a temperature of 2 °C to 8 °C.

(*S*)-(–)-α-Methylbenzyl isocyanate. C_9H_9NO. (M_r 147.2). *1170200.* [14649-03-7]. (–)-(*S*)-α-Methylbenzyl isocyanate. (–)-[(1*S*)-1-Isocyanatoethyl]benzene. (–)-(1*S*)-1-Phenylethyl isocyanate.

Content: minimum 99.0 per cent.

Colourless liquid.

d_{20}^{20}: about 1.045.

n_D^{20}: about 1.514.

bp: 55 °C to 56 °C at 2.5 mm Hg.

Enantiomeric purity: minimum 99.5 per cent.

Storage: at a temperature of 2 °C to 8 °C.

NOTE: do not use the reagent if it is coloured.

2-Methylbutane. C_5H_{12}. (M_r 72.2). *1099500.* [78-78-4]. Isopentane.

Content: minimum 99.5 per cent of C_5H_{12}.

Very flammable colourless liquid.

d_{20}^{20}: about 0.621.

n_D^{20}: about 1.354.

bp: about 29 °C.

Water (2.5.12): maximum 0.02 per cent.

Residue on evaporation: maximum 0.0003 per cent.

Minimum transmittance (2.2.25) using *water R* as compensation liquid: 50 per cent at 210 nm, 85 per cent at 220 nm, 98 per cent at 240 nm and at higher wavelengths.

2-Methylbut-2-ene. C_5H_{10}. (M_r 70.1). *1055400.* [513-35-9].

Very flammable liquid, practically insoluble in water, miscible with ethanol (96 per cent).

bp: 37.5 °C to 38.5 °C.

Methyl caprate. *1054000.*

See *Methyl decanoate R*.

Methyl caproate. $C_7H_{14}O_2$. (M_r 130.2). *1120300.* [106-70-7]. Methyl hexanoate.

d_{20}^{20}: about 0.885.

n_D^{20}: about 1.405.

bp: 150 °C to 151 °C.

Methyl caprylate. $C_9H_{18}O_2$. (M_r 158.2). *1120400.* [111-11-5]. Methyl octanoate.

d_{20}^{20}: about 0.876.

n_D^{20}: about 1.417.

bp: 193 °C to 194 °C.

Methylcellulose 450. *1055500.* [9004-67-5].

See *Methylcellulose (0345)*.

Nominal viscosity: 450 mPa·s.

Methyl cinnamate. $C_{10}H_{10}O_2$. (M_r 162.2). *1099400.* [103-26-4].

Colourless crystals practically insoluble in water, soluble in ethanol (96 per cent).

n_D^{20}: about 1.56.

bp: about 260 °C.

mp: 34 °C to 36 °C.

Methyl decanoate. $C_{11}H_{22}O_2$. (M_r 186.3). *1054000.* [110-42-9]. Methyl *n*-decanoate.

Content: minimum 99.0 per cent.

Clear, colourless or yellow liquid, soluble in light petroleum.

d_{20}^{20}: 0.871 to 0.876.

n_D^{20}: 1.425 to 1.426.

Foreign substances. Gas chromatography (*2.2.28*), injecting equal volumes of each of the following:

A 0.02 g/L solution of the substance to be examined in *carbon disulfide R* (solution A), a 2 g/L solution of the substance to be examined in *carbon disulfide R* (solution B), and *carbon disulfide R* (solution C). Carry out the chromatographic

procedure under the conditions of the test for butylated hydroxytoluene prescribed in the monograph *Wool fat (0134)*. The total area of any peaks, apart from the solvent peak and the principal peak, in the chromatogram obtained with solution B is less than the area of the principal peak in the chromatogram obtained with solution A.

Methyldopa, racemic. $C_{10}H_{13}NO_4,1^1/_2H_2O$. ($M_r$ 238.2). *1175100.*
Mixture of equal volumes of (2*S*)- and (2*R*)-2-amino-3-(3,4-dihydroxyphenyl)-2-methylpropanoic acids.

3-*O*-Methyldopamine hydrochloride. $C_9H_{14}ClNO_2$. (M_r 203.7). *1055600.* [1477-68-5]. 4-(2-Aminoethyl)-2-methoxyphenol hydrochloride.
mp: 213 °C to 215 °C.

4-*O*-Methyldopamine hydrochloride. $C_9H_{14}ClNO_2$. (M_r 203.7). *1055700.* [645-33-0]. 5-(2-Aminoethyl)-2-methoxyphenol hydrochloride.
mp: 207 °C to 208 °C.

Methylenebisacrylamide. $C_7H_{10}N_2O_2$. (M_r 154.2). *1056000.* [110-26-9]. *N,N'*-Methylenebispropenamide.
Fine, white or almost white powder, slightly soluble in water, soluble in ethanol (96 per cent).
mp: 300 °C, with decomposition.

Methylene blue. $C_{16}H_{18}ClN_3S,xH_2O$. (M_r 319.9 for the anhydrous substance). *1055800.* [7220-79-3].
Schultz No. 1038.
Colour Index No. 52015.
3,7-Dimethylaminophenothiazin-5-ium chloride.
It occurs in different hydrated forms and may contain up to 22 per cent of water. A dark-green or bronze, crystalline powder, freely soluble in water, soluble in ethanol (96 per cent).

Methylene chloride. CH_2Cl_2. (M_r 84.9). *1055900.* [75-09-2]. Dichloromethane.
Colourless liquid, sparingly soluble in water, miscible with ethanol (96 per cent).
bp: 39 °C to 42 °C.
Methylene chloride used in fluorimetry complies with the following additional test.
Fluorescence. Under irradiation at 365 nm, the fluorescence (*2.2.21*) measured at 460 nm in a 1 cm cell is not more intense than that of a solution containing 0.002 ppm of *quinine R* in *0.5 M sulfuric acid* measured in the same conditions.

Methylene chloride, acidified. *1055901.*
To 100 mL of *methylene chloride R* add 10 mL of *hydrochloric acid R*, shake, allow to stand and separate the two layers. Use the lower layer.

Methyl eicosenoate. $C_{21}H_{40}O_2$. (M_r 324.5). *1120500.* [2390-09-2]. (11*Z*)-eicos-11-enoate.

Methyl erucate. $C_{23}H_{44}O_2$. (M_r 352.6). *1146100.* [1120-34-9]. Methyl *cis*-13-docosenoate.
d_{20}^{20}: about 0.871.
n_D^{20}: about 1.456.

3-*O*-Methylestrone. $C_{19}H_{24}O_2$. (M_r 284.4). *1137000.* [1624-62-0]. 3-Methoxy-1,3,5(10)-estratrien-17-one.
White to yellowish-white powder.
$[\alpha]_D^{20}$: about + 157.
mp: about 173 °C.

Methyl ethyl ketone. C_4H_8O. (M_r 72.1). *1054100.* [78-93-3]. Ethyl methyl ketone. 2-Butanone.
Clear, colourless, flammable liquid, very soluble in water, miscible with ethanol (96 per cent).
d_{20}^{20}: about 0.81.
bp: 79 °C to 80 °C.

Methyl green. $C_{26}H_{33}Cl_2N_3$. (M_r 458.5). *1054200.* [7114-03-6].
Schultz No. 788.
Colour Index No. 42585.
4-[[4-(Dimethyl-amino)phenyl][4-(dimethyliminio)cyclohexa-2,5-dienylidene]-methylphenyl]trimethylammonium dichloride.
Green powder, soluble in water, soluble in sulfuric acid giving a yellow solution turning green on dilution with water.

Methyl green-iodomercurate paper. *1054201.*
Immerse thin strips of suitable filter paper in a 40 g/L solution of *methyl green R* and allow to dry in air. Immerse the strips for 1 h in a solution containing 140 g/L of *potassium iodide R* and 200 g/L of *mercuric iodide R*. Wash with *distilled water R* until the washings are practically colourless and allow to dry in air.
Storage: protected from light; use within 48 h.

Methyl 4-hydroxybenzoate. *1055000.* [99-76-3].
See *Methyl parahydroxybenzoate R*.

1-Methylimidazole. $C_4H_6N_2$. (M_r 82.1). *1139700.* [616-47-7]. 1-Methyl-1*H*-imidazole.
Colourless or slightly yellowish liquid.
n_D^{20}: about 1.495.
bp: 195 °C to 197 °C.
Storage: in an airtight container, protected from light.

1-Methylimidazole R1. *1139701.*
Complies with the requirements prescribed for *1-methylimidazole R* with the following additional requirement.
Content: minimum 95.0 per cent.

2-Methylimidazole. $C_4H_6N_2$. (M_r 82.1). *1143400.* [693-98-1].
White or almost white, crystalline powder.
mp: about 145 °C.

Methyl iodide. CH_3I. (M_r 141.9). *1166400.* [74-88-4]. Iodomethane.

Methyl isobutyl ketone. $C_6H_{12}O$. (M_r 100.2). *1054300.* [108-10-1]. 4-Methyl-2-pentanone.
Clear, colourless liquid, slightly soluble in water, miscible with most organic solvents.
d_{20}^{20}: about 0.80.
bp: about 115 °C.
Distillation range (*2.2.11*). Distil 100 mL. The range of temperature of distillation from 1 mL to 95 mL of distillate does not exceed 4.0 °C.
Residue on evaporation: maximum 0.01 per cent, determined by evaporating on a water-bath and drying at 100-105 °C.

Methyl isobutyl ketone R1. *1054301.*
Shake 50 mL of freshly distilled *methyl isobutyl ketone R* with 0.5 mL of *hydrochloric acid R1* for 1 min. Allow the phases to separate and discard the lower phase. Prepare immediately before use.

Methyl isobutyl ketone R3. *1054302.*
Complies with the requirements for *methyl isobutyl ketone R* and with the following limits.
Cr: maximum 0.02 ppm.
Cu: maximum 0.02 ppm.
Pb: maximum 0.1 ppm.
Ni: maximum 0.02 ppm.
Sn: maximum 0.1 ppm.

Methyl laurate. $C_{13}H_{26}O_2$. (M_r 214.4). *1054400.* [111-82-0]. Methyl dodecanoate.
Content: minimum 98.0 per cent, determined by gas chromatography (*2.4.22*).

Colourless or yellow liquid, soluble in ethanol (96 per cent) and in light petroleum.
d_{20}^{20}: about 0.87.
n_D^{20}: about 1.431.
mp: about 5 °C.

Methyl lignocerate. $C_{25}H_{50}O_2$. (M_r 382.7). *1120600.* [2442-49-1]. Methyl tetracosanoate.
Flakes.
mp: about 58 °C.

Methyl linoleate. $C_{19}H_{34}O_2$. (M_r 294.5). *1120700.* [112-63-0]. Methyl (9*Z*,12*Z*)-octadeca-9,12-dienoate.
d_{20}^{20}: about 0.888.
n_D^{20}: about 1.466.
bp: 207 °C to 208 °C.

Methyl linolenate. $C_{19}H_{32}O_2$. (M_r 292.5). *1120800.* [301-00-8]. Methyl (9*Z*,12*Z*,15*Z*)-octadeca-9,12,15-trienoate.
d_{20}^{20}: about 0.901.
n_D^{20}: about 1.471.
bp: about 207 °C.

Methyl γ-linolenate. $C_{19}H_{32}O_2$. (M_r 292.5). *1158400.* [16326-32-2]. Methyl (6*Z*,9*Z*,12*Z*)-octadeca-6,9,12-trienoate.
Content: minimum 99.0 per cent, determined by gas chromatography.

Methyl margarate. $C_{18}H_{36}O_2$. (M_r 284.5). *1120900.* [1731-92-6]. Methyl heptadecanoate.
White or almost white powder.
mp: 32 °C to 34 °C.
Methyl margarate used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*
Content: minimum 97 per cent, calculated by the normalisation procedure.

Methyl methacrylate. $C_5H_8O_2$. (M_r 100.1). *1054500.* [80-62-6]. Methyl 2-methylprop-2-enoate.
Colourless liquid.
n_D^{20}: about 1.414.
bp: about 100 °C.
mp: about – 48 °C.
It contains a suitable stabilising reagent.

Methyl *N*-methylanthranilate. $C_9H_{11}NO_2$. (M_r 165.2). *1164600.* [85-91-6]. Methyl 2-(methylamino)benzoate.
Pale yellow liquid.
d_4^{20}: about 1.128.
n_D^{20}: about 1.579.
bp: 255 °C to 258 °C.
Methyl N-methylanthranilate used in gas chromatography complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Mandarin oil (2355).*
Test solution. The substance to be examined.
Content: minimum 97 per cent, calculated by the normalisation procedure.

Methyl myristate. $C_{15}H_{30}O_2$. (M_r 242.4). *1054600.* [124-10-7]. Methyl tetradecanoate.
Content: minimum 98.0 per cent, determined by gas chromatography (*2.4.22*).
Colourless or slightly yellow liquid, soluble in ethanol (96 per cent) and in light petroleum.
d_{20}^{20}: about 0.87.
n_D^{20}: about 1.437.
mp: about 20 °C.

Methyl nervonate. *1144800.* [2733-88-2].
See *Tetracos-15-enoic acid methyl ester R.*

2-Methyl-5-nitroimidazole. $C_4H_5N_3O_2$. (M_r 127.1). *1056100.* [88054-22-2].
White to light yellow powder.
mp: 252 °C to 254 °C.
Content: minimum 98.0 per cent.

Methyl oleate. $C_{19}H_{36}O_2$. (M_r 296.4). *1054700.* [112-62-9]. Methyl (*Z*)-octadec-9-enoate.
Content: minimum 98.0 per cent, determined by gas chromatography (*2.4.22*).
Colourless or slightly yellow liquid, soluble in ethanol (96 per cent) and in light petroleum.
d_{20}^{20}: about 0.88.
n_D^{20}: about 1.452.

Methyl orange. $C_{14}H_{14}N_3NaO_3S$. (M_r 327.3). *1054800.* [547-58-0].
Schultz No. 176.
Colour Index No. 13025.
Sodium 4′-(dimethylamino)azobenzene-4-sulfonate.
Orange-yellow, crystalline powder, slightly soluble in water, practically insoluble in ethanol (96 per cent).

Methyl orange mixed solution. *1054801.*
Dissolve 20 mg of *methyl orange R* and 0.1 g of *bromocresol green R* in 1 mL of *0.2 M sodium hydroxide* and dilute to 100 mL with *water R.*
Colour change: pH 3.0 (orange) to pH 4.4 (olive-green).

Methyl orange solution. *1054802.*
Dissolve 0.1 g of *methyl orange R* in 80 mL of *water R* and dilute to 100 mL with *ethanol (96 per cent) R.*
Test for sensitivity. A mixture of 0.1 mL of the methyl orange solution and 100 mL of *carbon dioxide-free water R* is yellow. Not more than 0.1 mL of *1 M hydrochloric acid* is required to change the colour to red.
Colour change: pH 3.0 (red) to pH 4.4 (yellow).

Methyl palmitate. $C_{17}H_{34}O_2$. (M_r 270.5). *1054900.* [112-39-0]. Methyl hexadecanoate.
Content: minimum 98.0 per cent, determined by gas chromatography (*2.4.22*).
White or yellow, crystalline mass, soluble in ethanol (96 per cent) and in light petroleum.
mp: about 30 °C.

Methyl palmitoleate. $C_{17}H_{32}O_2$. (M_r 268.4). *1121000.* [1120-25-8]. Methyl (9*Z*)-hexadec-9-enoate.
d_{20}^{20}: about 0.876.
n_D^{20}: about 1.451.

Methyl parahydroxybenzoate. *1055000.* [99-76-3].
See *Methyl parahydroxybenzoate (0409).*

Methyl pelargonate. $C_{10}H_{20}O_2$. (M_r 172.3). *1143500.* [1731-84-6]. Methyl nonanoate.
Clear, colourless liquid.
d_4^{20}: about 0.873.
n_D^{20}: about 1.422.
bp: 91 °C to 92 °C.
Methyl pelargonate used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

3-Methylpentan-2-one. $C_6H_{12}O$. (M_r 100.2). *1141100.* [565-61-7].
Colourless, flammable liquid.
d_{20}^{20}: about 0.815.
n_D^{20}: about 1.400.
bp: about 118 °C

4-Methylpentan-2-ol. $C_6H_{14}O$. (M_r 102.2). *1114300.* [108-11-2].
Clear, colourless, volatile liquid.
d_4^{20}: about 0.802.
n_D^{20}: about 1.411.
bp: about 132 °C.

Methylphenyloxazolylbenzene. $C_{26}H_{20}N_2O_2$. (M_r 392.5). *1056200.* [3073-87-8]. 1,4-Bis[2-(4-methyl-5-phenyl)oxazolyl]benzene.
Fine, greenish-yellow powder with a blue fluorescence or small crystals, soluble in ethanol (96 per cent), sparingly soluble in xylene.
mp: about 233 °C.
Methylphenyloxazolylbenzene used for liquid scintillation is of a suitable analytical grade.

1-Methyl-4-phenyl-1,2,3,6-tetrahydropyridine. $C_{12}H_{15}N$. (M_r 173.3). *1137100.* [28289-54-5]. MPTP.
White or almost white, crystalline powder, slightly soluble in water.
mp: about 41 °C.

Methylpiperazine. $C_5H_{12}N_2$. (M_r 100.2). *1056300.* [109-01-3]. 1-Methylpiperazine.
Colourless liquid, miscible with water and with ethanol (96 per cent).
d_{20}^{20}: about 0.90.
n_D^{20}: about 1.466.
bp: about 138 °C.

4-(4-Methylpiperidin-1-yl)pyridine. $C_{11}H_{16}N_2$. (M_r 176.3). *1114400.* [80965-30-6].
Clear liquid.
n_D^{20}: about 1.565.

2-Methylpropanol. $C_4H_{10}O$. (M_r 74.1). *1056400.* [78-83-1]. Isobutyl alcohol. 2-Methylpropan-1-ol.
Clear colourless liquid, soluble in water, miscible with ethanol (96 per cent).
d_{20}^{20}: about 0.80.
n_D^{15}: 1.397 to 1.399.
bp: about 107 °C.
Distillation range (*2.2.11*). Not less than 96 per cent distils between 107 °C and 109 °C.

2-Methyl-2-propanol. $C_4H_{10}O$. (M_r 74.1). *1056500.* [75-65-0]. 1,1-Dimethyl ethyl alcohol. *tert*-Butyl alcohol.
Clear, colourless liquid or crystalline mass, soluble in water, miscible with ethanol (96 per cent).
Freezing point (*2.2.18*): about 25 °C.
Distillation range (*2.2.11*). Not less than 95 per cent distils between 81 °C and 83 °C.

(15*R*)-15-Methylprostaglandin $F_{2\alpha}$. $C_{21}H_{36}O_5$. (M_r 368.5). *1159900.* [35864-81-4]. (5*Z*)-7-[(1*R*,2*R*,3*R*,5*S*)-3,5-Dihydroxy-2-[(1*E*)-(3*R*)-3-hydroxy-3-methyloct-1-enyl]cyclopentyl]hept-5-enoic acid.
Available as a 10 g/L solution in *methyl acetate R*.
Storage: at a temperature below – 15 °C.

***N*-Methylpyrrolidine.** $C_5H_{11}N$. (M_r 85.2). *1164700.* [120-94-5].
Content: minimum 97.0 per cent.
bp: about 80 °C.

***N*-Methylpyrrolidone.** C_5H_9NO. (M_r 99.1). *1164800.* [872-50-4]. 1-Methylpyrrolidin-2-one.
d_{20}^{20}: about 1.028.
bp: about 202 °C.
mp: about – 24 °C.

Methyl red. $C_{15}H_{15}N_3O_2$. (M_r 269.3). *1055100.* [493-52-7].
Schultz No. 250.
Colour Index No. 13020.
2-(4-Dimethylamino-phenylazo)benzoic acid.
Dark-red powder or violet crystals, practically insoluble in water, soluble in ethanol (96 per cent).

Methyl red mixed solution. *1055101.*
Dissolve 0.1 g of *methyl red R* and 50 mg of *methylene blue R* in 100 mL of *ethanol (96 per cent) R*.
Colour change: pH 5.2 (red-violet) to pH 5.6 (green).

Methyl red solution. *1055102.*
Dissolve 50 mg in a mixture of 1.86 mL of *0.1 M sodium hydroxide* and 50 mL of *ethanol (96 per cent) R* and dilute to 100 mL with *water R*.
Test for sensitivity. To 0.1 mL of the methyl red solution add 100 mL of *carbon dioxide-free water R* and 0.05 mL of *0.02 M hydrochloric acid*. The solution is red. Not more than 0.1 mL of *0.02 M sodium hydroxide* is required to change the colour to yellow.
Colour change: pH 4.4 (red) to pH 6.0 (yellow).

Methyl salicylate. *1146200.* [119-36-8].
See *Methyl salicylate (0230)*

Methyl stearate. $C_{19}H_{38}O_2$. (M_r 298.5). *1055200.* [112-61-8]. Methyl octadecanoate.
Content: minimum 98.0 per cent, determined by gas chromatography (*2.4.22*).
White or yellow, crystalline mass, soluble in ethanol (96 per cent) and in light petroleum.
mp: about 38 °C.

Methylthymol blue. $C_{37}H_{40}N_2Na_4O_{13}S$. ($M_r$ 845). *1158500.* [1945-77-3]. Tetrasodium 2,2′,2″,2‴-[3*H*-2,1-benzoxathiol-3-ylidenebis[[6-hydroxy-2-methyl-5-(1-methylethyl)-3,1-phenylene]methylenenitrilo]]tetraacetate *S*,*S*-dioxide.
Produces a blue colour with calcium in alkaline solution.

Methylthymol blue mixture. *1158501.*
A mixture of 1 part of *methylthymol blue R* and 100 parts of *potassium nitrate R*.

***N*-Methyl-*m*-toluidine.** $C_8H_{11}N$. (M_r 121.2). *1175200.* [696-44-6]. *N*,3-Dimethylaniline. *N*,3-Dimethylbenzenamine. Methyl-*m*-tolylamine.
Content: minimum 97 per cent.

Methyl tricosanoate. $C_{24}H_{48}O_2$. (M_r 368.6). *1111500.* [2433-97-8]. Tricosanoic acid methyl ester.
Content: minimum 99.0 per cent.
White or almost white crystals, practically insoluble in water, soluble in hexane.
mp: 55 °C to 56 °C.

Methyl tridecanoate. $C_{14}H_{28}O_2$. (M_r 228.4). *1121100.* [1731-88-0].
Colourless or slightly yellow liquid, soluble in ethanol (96 per cent) and in light petroleum.
d_{20}^{20}: about 0.86.

n_D^{20}: about 1.441.

mp: about 6 °C.

Methyl 3,4,5-trimethoxybenzoate. $C_{11}H_{14}O_5$. (M_r 226.23). *1177200.* [1916-07-0].

***N*-Methyltrimethylsilyl-trifluoroacetamide.** $C_6H_{12}F_3NOSi$. (M_r 199.3). *1129600.* [24589-78-4]. 2,2,2-Trifluoro-*N*-methyl-*N*-(trimethylsilyl)acetamide.

n_D^{20}: about 1.380.

bp: 130 °C to 132 °C.

Minocycline hydrochloride. *1146300.*

See *Minocycline hydrochloride (1030).*

Molecular sieve. *1056600.*

Molecular sieve composed of sodium aluminosilicate. It is available as beads with a pore size of 0.4 nm and with a diameter of 2 mm.

Molecular sieve for chromatography. *1129700.*

Molecular sieve composed of sodium aluminosilicate. The pore size is indicated after the name of the reagent in the tests where it is used. If necessary, the particle size is also indicated.

Molybdovanadic reagent. *1056700.*

In a 150 mL beaker, mix 4 g of finely powdered *ammonium molybdate R* and 0.1 g of finely powdered *ammonium vanadate R*. Add 70 mL of *water R* and grind the particles using a glass rod. A clear solution is obtained within a few minutes. Add 20 mL of *nitric acid R* and dilute to 100 mL with *water R*.

Monodocosahexaenoin. $C_{25}H_{38}O_4$. (M_r 402.6). *1143600.* [124516-13-8]. Monoglyceride of docosahexaenoic acid (C22:6). Glycerol monodocosahexaenoate. (*all-Z*)-Docosa-4,7,10,13,16,19-hexaenoic acid, monoester with propane-1,2,3-triol.

Mordant black 11. $C_{20}H_{12}N_3NaO_7S$. (M_r 461.4). *1056800.* [1787-61-7].

Schultz No. 241.

Colour Index No. 14645.

Sodium 2-hydroxy-1-[(1-hydroxynaphth-2-yl)azo]-6-nitronaphthalene-4-sulfonate. Eriochrome black.

Brownish-black powder, soluble in water and in ethanol (96 per cent).

Storage: in an airtight container, protected from light.

Mordant black 11 triturate. *1056801.*

Mix 1 g of *mordant black 11 R* with 99 g of *sodium chloride R*.

Test for sensitivity. Dissolve 50 mg in 100 mL of *water R*. The solution is brownish-violet. On addition of 0.3 mL of *dilute ammonia R1* the solution turns blue. On the subsequent addition of 0.1 mL of a 10 g/L solution of *magnesium sulfate R*, it turns violet.

Storage: in an airtight container, protected from light.

Mordant black 11 triturate R1. *1056802.*

Mix 1.0 g of *mordant black 11 R*, 0.4 g of *methyl orange R* and 0.1 g of *sodium chloride R*.

Morphine hydrochloride. *1056900.*

See *Morphine hydrochloride (0097).*

Morpholine. C_4H_9NO. (M_r 87.1). *1057000.* [110-91-8]. Tetrahydro-1,4-oxazine.

Colourless, hygroscopic liquid, flammable, soluble in water and in ethanol (96 per cent).

d_{20}^{20}: about 1.01.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 126 °C and 130 °C.

Storage: in an airtight container.

Morpholine for chromatography. *1057001.*

Complies with the requirements prescribed for *morpholine R* with the following additional requirement.

Content: minimum 99.5 per cent.

Murexide. $C_8H_8N_6O_6,H_2O$. (M_r 302.2). *1137200.* 5,5′-Nitrilobis(pyrimidine-2,4,6(1*H*,3*H*,5*H*)-trione) monoammonium salt.

Brownish-red crystalline powder, sparingly soluble in cold water, soluble in hot water, practically insoluble in ethanol (96 per cent), soluble in solutions of potassium hydroxide or sodium hydroxide giving a blue colour.

Myosmine. $C_9H_{10}N_2$. (M_r 146.2). *1121200.* [532-12-7]. 3-(4,5-Dihydro-3*H*-pyrrol-2-yl)pyridine.

Colourless crystals.

mp: about 45 °C.

β-Myrcene. $C_{10}H_{16}$. (M_r 136.2). *1114500.* [123-35-3]. 7-Methyl-3-methylenocta-1,6-diene.

Oily liquid with a pleasant odour, practically insoluble in water, miscible with ethanol (96 per cent), soluble in glacial acetic acid. It dissolves in solutions of alkali hydroxides.

d_4^{20}: about 0.794.

n_D^{20}: about 1.470.

β-Myrcene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*

Test solution. The substance to be examined.

Content: minimum 90.0 per cent, calculated by the normalisation procedure.

Myristic acid. $C_{14}H_{28}O_2$. (M_r 228.4). *1143700.* [544-63-8]. Tetradecanoic acid.

Colourless or white or almost white flakes.

mp: about 58.5 °C.

Myristic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 97 per cent, calculated by the normalisation procedure.

Myristicine. $C_{11}H_{12}O_3$. (M_r 192.2). *1099600.* [607-91-0]. 5-Allyl-1-methoxy-2,3-methylenedioxybenzene. 4-Methoxy-6-(prop-2-enyl)-1,3-benzodioxole.

Oily colourless liquid, practically insoluble in water, slightly soluble in anhydrous ethanol, miscible with toluene and with xylene.

d_{20}^{20}: about 1.144.

n_D^{20}: about 1.540.

bp: 276 °C to 277 °C.

mp: about 173 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Star anise (1153)*; the chromatogram shows only one principal spot.

Myristicine used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Nutmeg oil (1552).*

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Storage: protected from light.

Myristyl alcohol. $C_{14}H_{30}O$. (M_r 214.4). *1121300.* [112-72-1]. 1-Tetradecanol.

d_{20}^{20}: about 0.823.

mp: 38 °C to 40 °C.

Myrtillin. $C_{21}H_{21}ClO_{12}$. (M_r 500.8). *1172300.* [6906-38-3]. Delphinidin 3-*O*-glucoside chloride.

Naphthalene. $C_{10}H_8$. (M_r 128.2). *1057100.* [91-20-3].

White or almost white crystals, practically insoluble in water, soluble in ethanol (96 per cent).

mp: about 80 °C.

Naphthalene used for liquid scintillation is of a suitable analytical grade.

Naphtharson. $C_{16}H_{11}AsN_2Na_2O_{10}S_2$. ($M_r$ 576.3). *1121400.* [3688-92-4]. Thorin. Disodium 4-[(2-arsonophenyl)azo]-3-hydroxynaphthalene-2,7-disulfonate.

Red powder, soluble in water.

Naphtharson solution. *1121401.*

A 0.58 g/L solution.

Test for sensitivity. To 50 mL of *ethanol (96 per cent) R*, add 20 mL of *water R*, 1 mL of *0.05 M sulfuric acid* and 1 mL of the naphtharson solution. Titrate with *0.025 M barium perchlorate*; the colour changes from orange-yellow to orange-pink.

Storage: protected from light; use within 1 week.

α-Naphthol. $C_{10}H_8O$. (M_r 144.2). *1057300.* [90-15-3]. 1-Naphthol.

White or almost white, crystalline powder or colourless or white or almost white crystals, darkening on exposure to light, slightly soluble in water, freely soluble in ethanol (96 per cent).

mp: about 95 °C.

Storage: protected from light.

α-Naphthol solution. *1057301.*

Dissolve 0.10 g of *α-naphthol R* in 3 mL of a 150 g/L solution of *sodium hydroxide R* and dilute to 100 mL with *water R*. Prepare immediately before use.

β-Naphthol. $C_{10}H_8O$. (M_r 144.2). *1057400.* [135-19-3]. 2-Naphthol.

White or slightly pink plates or crystals, very slightly soluble in water, very soluble in ethanol (96 per cent).

mp: about 122 °C.

Storage: protected from light.

β-Naphthol solution. *1057401.*

Dissolve 5 g of freshly recrystallised *β-naphthol R* in 40 mL of *dilute sodium hydroxide solution R* and dilute to 100 mL with *water R*. Prepare immediately before use.

β-Naphthol solution R1. *1057402.*

Dissolve 3.0 mg of *β-naphthol R* in 50 mL of *sulfuric acid R* and dilute to 100.0 mL with the same acid. Use the recently prepared solution.

Naphtholbenzein. $C_{27}H_{18}O_2$. (M_r 374.4). *1057600.* [145-50-6]. α-Naphtholbenzein. 4-[(4-Hydroxynaphthalen-1-yl)(phenyl)methylidene] naphthalen-1(4*H*)-one.

Brownish-red powder or shiny brownish-black crystals, practically insoluble in water, soluble in ethanol (96 per cent) and in glacial acetic acid.

Naphtholbenzein solution. *1057601.*

A 2 g/L solution in *anhydrous acetic acid R*.

Test for sensitivity. To 50 mL of *glacial acetic acid R* add 0.25 mL of the naphtholbenzein solution. The solution is brownish-yellow. Not more than 0.05 mL of *0.1 M perchloric acid* is required to change the colour to green.

Naphthol yellow. $C_{10}H_5N_2NaO_5$. (M_r 256.2). *1136600.* 2,4-Dinitro-1-naphthol, sodium salt.

Orange-yellow powder or crystals, freely soluble in water, slightly soluble in ethanol (96 per cent).

Naphthol yellow S. $C_{10}H_4N_2Na_2O_8S$. (M_r 358.2). *1143800.* [846-70-8].

Colour Index No. 10316.

8-Hydroxy-5,7-dinitro-2-naphthalenesulfonic acid disodium salt. Disodium 5,7-dinitro-8-oxidonaphthalene-2-sulfonate.

Yellow or orange-yellow powder, freely soluble in water.

1-Naphthylacetic acid. $C_{12}H_{10}O_2$. (M_r 186.2). *1148400.* [86-87-3]. (Naphthalen-1-yl)acetic acid.

White or yellow crystalline powder, very slightly soluble in water, freely soluble in acetone.

mp: about 135 °C.

Naphthylamine. $C_{10}H_9N$. (M_r 143.2). *1057700.* [134-32-7]. 1-Naphthylamine.

White or almost white, crystalline powder, turning pink on exposure to light and air, slightly soluble in water, freely soluble in ethanol (96 per cent).

mp: about 51 °C.

Storage: protected from light.

Naphthylethylenediamine dihydrochloride. $C_{12}H_{16}Cl_2N_2$. (M_r 259.2). *1057800.* [1465-25-4]. *N*-(1-Naphthyl)ethylenediamine dihydrochloride.

It may contain methanol of crystallisation.

White or yellowish-white powder, soluble in water, slightly soluble in ethanol (96 per cent).

Naphthylethylenediamine dihydrochloride solution. *1057801.*

Dissolve 0.1 g of *naphthylethylenediamine dihydrochloride R* in *water R* and dilute to 100 mL with the same solvent. Prepare immediately before use.

Naringin. $C_{27}H_{32}O_{14}$. (M_r 580.5). *1137300.* [10236-47-2]. 7-[[2-*O*-(6-Deoxy-α-L-mannopyranosyl)-β-D-glucopyranosyl]oxy]-5-hydroxy-2-(4-hydroxyphenyl)-2,3-dihydro-4*H*–chromen-4-one.

White or almost white crystalline powder, slightly soluble in water, soluble in methanol and in dimethylformamide.

mp: about 171 °C.

Absorbance (*2.2.25*). Naringin dissolved in a 5 g/L solution of *dimethylformamide R* in *methanol R* shows an absorption maximum at 283 nm.

***trans*-Nerolidol.** $C_{15}H_{26}O$. (M_r 222.4). *1107900.* [40716-66-3]. 3,7,11-Trimethyldodeca-1,6,10-trien-3-ol.

Slightly yellow liquid, slight odour of lily and lily of the valley, practically insoluble in water and in glycerol, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.876.

n_D^{20}: about 1.479.

bp_{12}: 145 °C to 146 °C.

trans-Nerolidol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Bitter-orange-flower oil (1175).*

Test solution. The substance to be examined.

Content: minimum 90.0 per cent, calculated by the normalisation procedure.

Neryl acetate. $C_{12}H_{20}O_2$. (M_r 196.3). *1108000.* [141-12-8]. (*Z*)-3,7-Dimethylocta-2,6-dienyl acetate.

Colourless, oily liquid.

d_{20}^{20}: about 0.907.

n_D^{20}: about 1.460.

bp_{25}: 134 °C.

Neryl acetate used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Bitter-orange-flower oil (1175).*

Test solution. The substance to be examined.

Content: minimum 93.0 per cent, calculated by the normalisation procedure.

Nickel-aluminium alloy. *1058100.*

Contains 48 per cent to 52 per cent of aluminium (Al; A_r 26.98) and 48 per cent to 52 per cent of nickel (Ni; A_r 58.70).

Before use, reduce to a fine powder (180) (*2.9.12*).

It is practically insoluble in water and soluble in mineral acids.

Nickel-aluminium alloy (halogen-free). *1118100.*

Contains 48 per cent to 52 per cent of aluminium (Al; A_r 26.98) and 48 per cent to 52 per cent of nickel (Ni; A_r 58.71).

Fine, grey powder, practically insoluble in water, soluble in mineral acids with formation of salts.
Chlorides: maximum 10 ppm.

Dissolve 0.400 g in 40 mL of a mixture of 67 volumes of *sulfuric acid R* and 33 volumes of *dilute nitric acid R*. Evaporate the solution nearly to dryness, dissolve the residue in *water R* and dilute to 20.0 mL with the same solvent. To one half-aliquot of the solution, add 1.0 mL of *0.1 M silver nitrate*. Filter after 15 min and add 0.2 mL of sodium chloride solution (containing 10 µg of chlorides per millilitre) to the filtrate. After 5 min the solution is more opalescent than a mixture of the second half-aliquot of the solution with 1.0 mL of *0.1 M silver nitrate*.

Nickel chloride. $NiCl_2$. (M_r 129.6). *1057900.* [7718-54-9].
Nickel chloride, anhydrous.

Yellow, crystalline powder, very soluble in water, soluble in ethanol (96 per cent). It sublimes in the absence of air and readily absorbs ammonia. The aqueous solution is acid.

Nickel nitrate hexahydrate. $Ni(NO_3)_2,6H_2O$. (M_r 290.8). *1175300.* [13478-00-7].

Nickel sulfate. $NiSO_4,7H_2O$. (M_r 280.9). *1058000.* [10101-98-1].
Nickel sulfate heptahydrate.

Green, crystalline powder or crystals, freely soluble in water, slightly soluble in ethanol (96 per cent).

Nicotinamide-adenine dinucleotide. $C_{21}H_{27}N_7O_{14}P_2$. (M_r 663). *1108100.* [-84-9]. NAD^+.

White or almost white powder, very hygroscopic, freely soluble in water.

Nicotinamide-adenine dinucleotide solution. *1108101.*

Dissolve 40 mg of *nicotinamide-adenine dinucleotide R* in *water R* and dilute to 10 mL with the same solvent. Prepare immediately before use.

Nicotinic acid. *1158600.* [59-67-6].

See *Nicotinic acid (0459)*.

Nile blue A. $C_{20}H_{21}N_3O_5S$. (M_r 415.5). *1058200.* [3625-57-8].
Schultz No. 1029.
Colour Index No. 51180.
5-Amino-9-(diethylamino)benzo[*a*]phenoxazinylium hydrogen sulfate.

Green, crystalline powder with a bronze lustre, sparingly soluble in ethanol (96 per cent), in glacial acetic acid and in pyridine.

Absorbance (*2.2.25*). A 0.005 g/L solution in *ethanol (50 per cent V/V) R* shows an absorption maximum at 640 nm.

Nile blue A solution. *1058201.*

A 10 g/L solution in *anhydrous acetic acid R*.

Test for sensitivity. To 50 mL of *anhydrous acetic acid R* add 0.25 mL of the Nile blue A solution. The solution is blue. On the addition of 0.1 mL of *0.1 M perchloric acid*, the colour changes to blue-green.

Colour change: pH 9.0 (blue) to pH 13.0 (red).

Ninhydrin. $C_9H_4O_3,H_2O$. (M_r 178.1). *1058300.* [485-47-2].
1,2,3-Indanetrione monohydrate.

White or very pale yellow, crystalline powder, soluble in water and in ethanol (96 per cent).

Storage: protected from light.

Ninhydrin and stannous chloride reagent. *1058301.*

Dissolve 0.2 g of *ninhydrin R* in 4 mL of hot *water R*, add 5 mL of a 1.6 g/L solution of *stannous chloride R*, allow to stand for 30 min, then filter and store at a temperature of 2 °C to 8 °C. Immediately before use dilute 2.5 mL of the solution with 5 mL of *water R* and 45 mL of *2-propanol R*.

Ninhydrin and stannous chloride reagent R1. *1058302.*

Dissolve 4 g of *ninhydrin R* in 100 mL of *ethylene glycol monomethyl ether R*. Shake gently with 1 g of *cation exchange resin R* (300 µm to 840 µm) and filter (solution A). Dissolve 0.16 g of *stannous chloride R* in 100 mL of *buffer solution pH 5.5 R* (solution B). Immediately before use, mix equal volumes of each solution.

Ninhydrin solution. *1058303.*

A 2 g/L solution of *Ninhydrin R* in a mixture of 5 volumes of *dilute acetic acid R* and 95 volumes of *butanol R*.

Ninhydrin solution R1. *1058304.*

Dissolve 1.0 g of *ninhydrin R* in 50 mL of *ethanol (96 per cent) R* and add 10 mL of *glacial acetic acid R*.

Ninhydrin solution R2. *1058305.*

Dissolve 3 g of *ninhydrin R* in 100 mL of a 45.5 g/L solution of *sodium metabisulfite R*.

Ninhydrin solution R3. *1058306.*

A 4 g/L solution in a mixture of 5 volumes of *anhydrous acetic acid R* and 95 volumes of *butanol R*.

Nitrazepam. *1143900.* [146-22-5].

See *Nitrazepam (0415)*.

Nitric acid. HNO_3. (M_r 63.0). *1058400.* [7697-37-2].

Content: 63.0 per cent *m/m* to 70.0 per cent *m/m*.

Clear, colourless or almost colourless liquid, miscible with water.

d_{20}^{20}: 1.384 to 1.416.

A 10 g/L solution is strongly acid and gives the reaction of nitrates (*2.3.1*).

Appearance. Nitric acid is clear (*2.2.1*) and not more intensely coloured than reference solution Y_6 (*Method II, 2.2.2*).

Chlorides (*2.4.4*): maximum 0.5 ppm.

To 5 g add 10 mL of *water R* and 0.3 mL of *silver nitrate solution R2* and allow to stand for 2 min protected from light. Any opalescence is not more intense than that of a standard prepared in the same manner using 13 mL of *water R*, 0.5 mL of *nitric acid R*, 0.5 mL of *chloride standard solution (5 ppm Cl) R* and 0.3 mL of *silver nitrate solution R2*.

Sulfates (*2.4.13*): maximum 2 ppm.

Evaporate 10 g to dryness with 0.2 g of *sodium carbonate R*. Dissolve the residue in 15 mL of *distilled water R*. Prepare the standard using a mixture of 2 mL of *sulfate standard solution (10 ppm SO_4) R* and 13 mL of *distilled water R*.

Arsenic (*2.4.2, Method A*): maximum 0.02 ppm.

Gently heat 50 g with 0.5 mL of *sulfuric acid R* until white fumes begin to evolve. To the residue add 1 mL of a 100 g/L solution of *hydroxylamine hydrochloride R* and dilute to 2 mL with *water R*. Prepare the standard using 1.0 mL of *arsenic standard solution (1 ppm As) R*.

Iron (*2.4.9*): maximum 1 ppm.

Dissolve the residue from the determination of sulfated ash in 1 mL of *dilute hydrochloric acid R* and dilute to 50 mL with *water R*. Dilute 5 mL of this solution to 10 mL with *water R*.

Heavy metals (*2.4.8*): maximum 2 ppm.

Dilute 10 mL of the solution prepared for the limit test for iron to 20 mL with *water R*. 12 mL of the solution complies with test A. Prepare the reference solution using *lead standard solution (2 ppm Pb) R*.

Sulfated ash: maximum 0.001 per cent.

Carefully evaporate 100 g to dryness. Moisten the residue with a few drops of *sulfuric acid R* and heat to dull red.

Assay. To 1.50 g add about 50 mL of *water R* and titrate with *1 M sodium hydroxide*, using 0.1 mL of *methyl red solution R* as indicator.

1 mL of *1 M sodium hydroxide* is equivalent to 63.0 mg of HNO_3.

Storage: protected from light.

Nitric acid, cadmium- and lead-free. *1058401.*

Complies with the requirements prescribed for *nitric acid R* and with the following additional test.

Test solution. To 100 g add 0.1 g of *anhydrous sodium carbonate R* and evaporate to dryness. Dissolve the residue in *water R* heating slightly, and dilute to 50.0 mL with the same solvent.

Cadmium: maximum 0.1 ppm.

Atomic absorption spectrometry (*2.2.23, Method II*).

Source: cadmium hollow-cathode lamp.

Wavelength: 228.8 nm.

Atomisation device: air-acetylene or air-propane flame.

Lead: maximum 0.1 ppm.

Atomic absorption spectrometry (*2.2.23, Method II*).

Source: lead hollow-cathode lamp.

Wavelength: 283.3 nm or 217.0 nm.

Atomisation device: air-acetylene flame.

Nitric acid, dilute. *1058402.*

Contains about 125 g/L of HNO_3 (M_r 63.0).

Dilute 20 g of *nitric acid R* to 100 mL with *water R*.

Nitric acid, dilute R1. *1058407.*

Dilute 40 g of *nitric acid R* to 100 mL with *water R*.

Nitric acid, dilute R2. *1058409.*

Dilute 30 g of *nitric acid R* to 100 mL with *water R*.

Nitric acid, heavy metal-free. *1058404.*

Complies with the requirements prescribed for *nitric acid R* with the following maximum contents of heavy metals.

As: 0.005 ppm.

Cd: 0.005 ppm.

Cu: 0.001 ppm.

Fe: 0.02 ppm.

Hg: 0.002 ppm.

Ni: 0.005 ppm.

Pb: 0.001 ppm.

Zn: 0.01 ppm.

Nitric acid, lead-free. *1058403.*

Complies with the requirements prescribed for *Nitric acid R* with the following additional test.

Lead: maximum 0.1 ppm.

Atomic absorption spectrometry (*2.2.23, Method II*).

Test solution. To 100 g add 0.1 g of *anhydrous sodium carbonate R* and evaporate to dryness. Dissolve the residue in *water R*, heating slightly, and dilute to 50.0 mL with the same solvent.

Source: lead hollow-cathode lamp.

Wavelength: 283.3 nm or 217.0 nm.

Atomisation device: air-acetylene flame.

Nitric acid, lead-free R1. *1058405.*

Nitric acid R containing not more than 1 µg/kg of lead.

Nitric acid, lead-free, dilute. *1058406.*

Dilute 5 g of *lead-free nitric acid R1* to 100 mL with *deionised distilled water R*.

Nitric acid, nickel-free. *1058408.*

Complies with the requirements prescribed for *nitric acid R* with the following additional requirement.

Nickel: maximum 0.005 ppm.

Nitric acid, fuming. *1058500.* [52583-42-3].

Clear, slightly yellowish liquid, fuming on contact with air.

d_{20}^{20}: about 1.5.

Nitrilotriacetic acid. $C_6H_9NO_6$. (M_r 191.1). *1137400.* [139-13-9].

White or almost white crystalline powder, practically insoluble in water and in most organic solvents.

mp: about 240 °C, with decomposition.

Nitroaniline. $C_6H_6N_2O_2$. (M_r 138.1). *1058600.* [100-01-6].

4-Nitroaniline.

Bright yellow, crystalline powder, very slightly soluble in water, sparingly soluble in boiling water, soluble in ethanol (96 per cent), forms water-soluble salts with strong mineral acids.

mp: about 147 °C.

Nitrobenzaldehyde. $C_7H_5NO_3$. (M_r 151.1). *1058700.* [552-89-6].

2-Nitrobenzaldehyde.

Yellow needles, slightly soluble in water, freely soluble in ethanol (96 per cent), volatile in steam.

mp: about 42 °C.

Nitrobenzaldehyde paper. *1058701.*

Dissolve 0.2 g of *nitrobenzaldehyde R* in 10 mL of a 200 g/L solution of *sodium hydroxide R*. Use the solution within 1 h. Immerse the lower half of a slow filter paper strip 10 cm long and 0.8-1 cm wide. Absorb the excess reagent between two sheets of filter paper. Use within a few minutes of preparation.

Nitrobenzaldehyde solution. *1058702.*

Add 0.12 g of powdered *nitrobenzaldehyde R* to 10 mL of *dilute sodium hydroxide solution R*; allow to stand for 10 min shaking frequently and filter. Prepare immediately before use.

Nitrobenzene. $C_6H_5NO_2$. (M_r 123.1). *1058800.* [98-95-3].

Colourless or very slightly yellow liquid, practically insoluble in water, miscible with ethanol (96 per cent).

bp: about 211 °C.

Dinitrobenzene. To 0.1 mL add 5 mL of *acetone R*, 5 mL of *water R* and 5 mL of *strong sodium hydroxide solution R*. Shake and allow to stand. The upper layer is almost colourless.

4-Nitrobenzoic acid. $C_7H_5NO_4$. (M_r 167.1). *1144000.* [62-23-7].

Yellow crystals.

mp: about 240 °C.

Nitrobenzoyl chloride. $C_7H_4ClNO_3$. (M_r 185.6). *1058900.* [122-04-3]. 4-Nitrobenzoyl chloride.

Yellow crystals or a crystalline mass, decomposing in moist air, completely soluble in sodium hydroxide solution giving a yellowish-orange colour.

mp: about 72 °C.

Nitrobenzyl chloride. $C_7H_6ClNO_2$. (M_r 171.6). *1059000.* [100-14-1]. 4-Nitrobenzyl chloride.

Pale-yellow crystals, lachrymatory, practically insoluble in water, very soluble in ethanol (96 per cent).

4-(4-Nitrobenzyl)pyridine. $C_{12}H_{10}N_2O_2$. (M_r 214.2). *1101900.* [1083-48-3].

Yellow powder.

mp: about 70 °C.

Nitrochromic reagent. *1059100.*

Dissolve 0.7 g of *potassium dichromate R* in *nitric acid R* and dilute to 100 mL with the same acid.

Nitroethane. $C_2H_5NO_2$. (M_r 75.1). *1059200.* [79-24-3].

Clear, oily, colourless liquid.

bp: about 114 °C.

Nitrofurantoin. *1099700.* [67-20-9].

See *Nitrofurantoin (0101)*.

(5-Nitro-2-furyl)methylene diacetate. $C_9H_9NO_7$. (M_r 243.2). *1099800.* [92-55-7]. Nitrofurfural diacetate. 5-Nitrofurfurylidene diacetate.

Yellow crystals.

mp: about 90 °C.

Nitrogen. N_2. (M_r 28.01). *1059300.* [7727-37-9].

Nitrogen, washed and dried.

Nitrogen gas mixture. *1136900.*

Nitrogen R containing 1 per cent *V/V* of each of the following gases: *carbon dioxide R2, carbon monoxide R1* and *oxygen R1*.

Nitrogen, oxygen-free. *1059600.*

Nitrogen R which has been freed from oxygen by passing it through *alkaline pyrogallol solution R*.

Nitrogen R1. N_2. (M_r 28.01). *1059400.* [7727-37-9].

Content: minimum 99.999 per cent *V/V*.

Carbon monoxide: less than 5 ppm.

Oxygen: less than 5 ppm.

Nitrogen for chromatography. N_2. (M_r 28.01). *1059500.* [7727-37-9].

Content: minimum 99.95 per cent *V/V*.

Nitrogen monoxide. NO. (M_r 30.01). *1108300.*

Content: minimum 98.0 per cent *V/V*.

Nitromethane. CH_3NO_2. (M_r 61.0). *1059700.* [75-52-5].

Clear, colourless, oily liquid, slightly soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: 1.132 to 1.134.

n_D^{20}: 1.381 to 1.383.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 100 °C and 103 °C.

Nitro-molybdovanadic reagent. *1060100.*

Solution A. Dissolve 10 g of *ammonium molybdate R* in *water R*, add 1 mL of *ammonia R* and dilute to 100 mL with *water R*.

Solution B. Dissolve 2.5 g of *ammonium vanadate R* in hot *water R*, add 14 mL of *nitric acid R* and dilute to 500 mL with *water R*.

To 96 mL of *nitric acid R* add 100 mL of solution A and 100 mL of solution B and dilute to 500 mL with *water R*.

4-Nitrophenol. $C_6H_5NO_3$. (M_r 139.1). *1146400.* [100-02-7]. *p*-Nitrophenol.

Content: minimum 95 per cent.

Colourless or slightly yellow powder, sparingly soluble in water and in methanol.

mp: about 114 °C.

***N*-Nitrosodiethanolamine.** $C_4H_{10}N_2O_3$. (M_r 134.1). *1129800.* [1116-54-7]. 2,2′-(Nitrosoimino)diethanol.

Yellow liquid, miscible with anhydrous ethanol.

n_D^{20}: about 1.485.

bp: about 125 °C.

***N*-Nitrosodiisopropanolamine.** $C_6H_{14}N_2O_3$. (M_r 162.2). *1176500.* [53609-64-6]. 1,1′-(Nitrosoimino)bispropan-2-ol.

bp: 122-124 °C.

Nitrosodipropylamine. $C_6H_{14}N_2O$. (M_r 130.2). *1099900.* [621-64-7]. Dipropylnitrosamine.

Liquid, soluble in anhydrous ethanol and in strong acids.

d_{20}^{20}: about 0.915.

bp: about 78 °C.

Appropriate grade for chemiluminescence determination.

Nitrosodipropylamine solution. *1099901.*

Inject 78.62 g of *anhydrous ethanol R* through the septum of a vial containing *nitrosodipropylamine R*. Dilute 1/100 in *anhydrous ethanol R* and place 0.5 mL aliquots in crimp-sealed vials.

Storage: in the dark at 5 °C.

Nitrotetrazolium blue. $C_{40}H_{30}Cl_2N_{10}O_6$. ($M_r$ 818). *1060000.* [298-83-9]. 3,3′-(3,3′-Dimethoxy-4,4′-diphenylene)di[2-(4-nitrophenyl)-5-phenyl-2*H*-tetrazolium] dichloride. *p*-Nitro-tetrazolium blue.

Crystals, soluble in methanol, giving a clear, yellow solution.

mp: about 189 °C, with decomposition.

Nitrous oxide. N_2O. (M_r 44.01). *1108500.*

Content: minimum 99.99 per cent *V/V*.

Nitrogen monoxide: less than 1 ppm.

Carbon monoxide: less than 1 ppm.

Nonivamide. $C_{17}H_{27}NO_3$. (M_r 293.4). *1148500.* [2444-46-4]. *N*-[(4-Hydroxy-3-methoxyphenyl)methyl]nonanamide.

White or almost white, crystalline powder, practically insoluble in cold water, freely soluble in anhydrous ethanol.

Nonivamide used in the test for nonivamide in the monograph Capsicum (1859) complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Capsicum (1859)*.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Nonylamine. $C_9H_{21}N$. (M_r 143.3). *1139800.* [112-20-9]. 1-Aminononane.

Corrosive, colourless, clear liquid.

d_4^{20}: about 0.788.

n_D^{20}: about 1.433.

Nordazepam. $C_{15}H_{11}ClN_2O$. (M_r 270.7). *1060200.* [1088-11-5]. 7-Chloro-2,3-dihydro-5-phenyl-1*H*-1,4-benzodiazepin-2-one.

White or pale yellow, crystalline powder, practically insoluble in water, slightly soluble in ethanol (96 per cent).

mp: about 216 °C.

DL-Norleucine. $C_6H_{13}NO_2$. (M_r 131.2). *1060300.* [616-06-8]. (*RS*)-2-Aminohexanoic acid.

Shiny crystals, sparingly soluble in water and in ethanol (96 per cent), soluble in acids.

Noscapine hydrochloride. *1060500.* [912-60-7].

See *Noscapine hydrochloride (0515)*.

Ochratoxin A solution. *1175700.*

50 µg/mL solution of (2*S*)-2-[[[(3*R*)-5-chloro-8-hydroxy-3-methyl-1-oxo-3,4-dihydro-1*H*-2-benzopyran-7-yl]carbonyl]amino)-3-phenylpropanoic acid (ochratoxin A) in a mixture of 1 volume of *acetic acid R* and 99 volumes of *benzene R*.

Octadecyl [3-[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-propionate]. $C_{35}H_{62}O_3$. (M_r 530.9). *1060600.* [2082-79-3]. Octadecyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate.

White or slightly yellowish, crystalline powder, practically insoluble in water, very soluble in acetone and in hexane, slightly soluble in methanol.

mp: 49 °C to 55 °C.

Octanal. $C_8H_{16}O$. (M_r 128.2). *1150400.* [124-13-0]. Octyl aldehyde.

Oily, colourless liquid. Practically insoluble in water.

Octanal used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Sweet orange oil (1811).*

Content: minimum 99 per cent, calculated by the normalisation procedure.

Octane. C_8H_{18}. (M_r 114.2). *1166500.* [111-65-9]. *n*-Octane.

Octanol. $C_8H_{18}O$. (M_r 130.2). *1060700.* [111-87-5]. 1-Octanol. Caprylic alcohol.

Colourless liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.828.

bp: about 195 °C.

3-Octanone. $C_8H_{16}O$. (M_r 128.2). *1114600.* [106-68-3]. Ethylpentylketone.

Colourless liquid with a characteristic odour.

d_{20}^{20}: about 0.822.

n_D^{20}: about 1.415.

bp: about 167 °C.

3-Octanone used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Lavender oil (1338).*

Test solution. The substance to be examined.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Octoxinol 10. $C_{34}H_{62}O_{11}$ (average). (M_r 647). *1060800.* [9002-93-1]. α-[4-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly-(oxyethylene).

Clear, pale-yellow, viscous liquid, miscible with water, with acetone and with ethanol (96 per cent), soluble in toluene.

Storage: in an airtight container.

Octylamine. $C_8H_{19}N$. (M_r 129.2). *1150500.* [111-86-4]. Octan-1-amine.

Colourless liquid.

d_{20}^{20}: about 0.782.

bp: 175 °C to 179 °C.

Oleamide. $C_{18}H_{35}NO$. (M_r 281.5). *1060900.* (*Z*)-Octadec-9-enoamide.

Yellowish or white powder or granules, practically insoluble in water, very soluble in methylene chloride, soluble in anhydrous ethanol.

mp: about 80 °C.

Oleic acid. $C_{18}H_{34}O_2$. (M_r 282.5). *1144100.* [112-80-1]. (9*Z*)-Octadec-9-enoic acid.

Clear, colourless liquid, practically insoluble in water.

d_4^{20}: about 0.891.

n_D^{20}: about 1.459.

mp: 13 °C to 14 °C.

Oleic acid used in the assay of total fatty acids in the monograph Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

Oleuropein. $C_{25}H_{32}O_{13}$. (M_r 540.5). *1152900.* [32619-42-4]. 2-(3,4-Dihydroxyphenyl)ethyl[(2*S*,3*E*,4*S*)-3-ethylidene-2-(b-d-glucopyranosyloxy)-5-(methoxycarbonyl)-3,4-dihydro-2*H*-pyran-4-yl]acetate.

Powder, soluble in methanol.

Oleuropein used in Olive leaf (1878) complies with the following test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Olive leaf (1878).*

Content: minimum 80 per cent, calculated by the normalisation procedure.

Oleyl alcohol. $C_{18}H_{36}O$. (M_r 268.5). *1156000.* [143-28-2]. (9*Z*)-octadec-9-en-1-ol.

bp: about 207 °C.

n_D^{20}: 1.460.

Content: minimum 85 per cent.

Olive oil. *1061000.* [8001-25-0].

See *Olive oil, virgin (0518).*

Oracet blue 2R. $C_{20}H_{14}N_2O_2$. (M_r 314.3). *1061100.* [4395-65-7].

Colour Index No. 61110.
1-Amino-4-(phenylamino)anthracene-9,10-dione.

mp: about 194 °C.

Orcinol. $C_7H_8O_2,H_2O$. (M_r 142.2). *1108700.* [6153-39-5]. 5-Methylbenzene-1,3-diol monohydrate.

Crystalline powder, sensitive to light.

bp: about 290 °C.

mp: 58 °C to 61 °C.

Organosilica polymer, amorphous, octadecylsilyl. *1144200.*

Synthetic, spherical hybrid particles, containing both inorganic (silica) and organic (organosiloxanes) components, chemically modified at the surface by trifunctionally bonded octadecylsilyl groups.

Organosilica polymer, amorphous, octadecylsilyl, end-capped. *1178600.*

Synthetic, spherical hybrid particles, containing both inorganic (silica) and organic (organosiloxanes) components, chemically modified at the surface by trifunctionally bonded octadecylsilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Organosilica polymer, amorphous, polar-embedded octadecylsilyl, end-capped. *1150600.*

Synthetic, spherical hybrid particles containing both inorganic (silica) and organic (organosiloxanes) components, chemically modified at the surface by the bonding of polar embedded octadecylsilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Organosilica polymer, amorphous, polar-embedded propyl-2-phenylsilyl, end-capped. *1178100.*

Synthetic, spherical hybrid particles containing both inorganic (silica) and organic (organosiloxanes) components, chemically modified at the surface by the bonding of polar-embedded propyl-2-phenylsilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Organosilica polymer for mass spectrometry, amorphous, octadecylsilyl, end-capped. *1164900.*

Synthetic, spherical hybrid particles containing both inorganic (silica) and organic (organosiloxanes) components. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Osmium tetroxide. OsO_4. (M_r 254.2). *1061200.* [20816-12-0].

Light-yellow needles or a yellow, crystalline mass, hygroscopic, light sensitive, soluble in water and in ethanol (96 per cent).

Storage: in an airtight container.

Osmium tetroxide solution. *1061201.*

A 2.5 g/L solution in *0.05 M sulfuric acid.*

Oxalic acid. $C_2H_2O_4,2H_2O$. (M_r 126.1). *1061400.* [6153-56-6]. Ethanedioic acid dihydrate.

White or almost white crystals, soluble in water, freely soluble in ethanol (96 per cent).

Oxalic acid and sulfuric acid solution. *1061401.*

A 50 g/L solution of *oxalic acid R* in a cooled mixture of equal volumes of *sulfuric acid R* and *water R*.

Oxazepam. *1144300.* [604-75-1].

See *Oxazepam (0778).*

Ox brain, acetone-dried. *1061300.*

Cut into small pieces a fresh ox brain previously freed from vascular and connective tissue. Place in *acetone R* for preliminary dehydration. Complete the dehydration by pounding in a mortar 30 g of this material with successive quantities, each of 75 mL, of *acetone R* until a dry powder is obtained after filtration. Dry at 37 °C for 2 h or until the odour of acetone is no longer present.

2,2′-Oxybis(*N*,*N*-dimethylethylamine). $C_8H_{20}N_2O$. (M_r 160.3). *1141200.* [3033-62-3]. bis(2-Dimethylaminoethyl) ether.

Colourless, corrosive liquid.

d_{20}^{20}: about 0.85.

n_D^{20}: about 1.430.

Oxygen. O_2. (M_r 32.00). *1108800.*

Content: minimum 99.99 per cent *V/V*.

Nitrogen and argon: less than 100 ppm.

Carbon dioxide: less than 10 ppm.

Carbon monoxide: less than 5 ppm.

Oxygen R1. O_2. (M_r 32.00). *1137600.*

Content: minimum 99 per cent *V/V*.

Oxytetracycline hydrochloride. *1146500.*

See *Oxytetracycline hydrochloride (0198).*

Palladium. Pd. (A_r 106.4). *1114700.* [7440-05-3].

Grey white metal, soluble in hydrochloric acid.

Palladium chloride. $PdCl_2$. (M_r 177.3). *1061500.* [7647-10-1].

Red crystals.

mp: 678 °C to 680 °C.

Palladium chloride solution. *1061501.*

Dissolve 1 g of *palladium chloride R* in 10 mL of warm *hydrochloric acid R*. Dilute the solution to 250 mL with a mixture of equal volumes of *dilute hydrochloric acid R* and *water R*. Dilute this solution immediately before use with 2 volumes of *water R*.

Palmitic acid. $C_{16}H_{32}O_2$. (M_r 256.4). *1061600.* [57-10-3]. Hexadecanoic acid.

White or almost white, crystalline scales, practically insoluble in water, freely soluble in hot ethanol (96 per cent).

mp: about 63 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Chloramphenicol palmitate (0473)*; the chromatogram shows only one principal spot.

Palmitic acid used in the assay of total fatty acids in the monograph Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

Palmitoleic acid. $C_{16}H_{30}O_2$. (M_r 254.4). *1144400.* [373-49-9]. (9*Z*)-Hexadec-9-enoic acid.

Clear, colourless liquid.

bp: about 162 °C.

Palmitoleic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848).*

Content: minimum 98 per cent, calculated by the normalisation procedure.

Palmityl alcohol. $C_{16}H_{34}O$. (M_r 242.4). *1156100.* [36653-82-4]. Cetyl alcohol. 1-Hexadecanol.

mp: about 48 °C.

Content: minimum 96 per cent.

Pancreas powder. *1061700.*

See *Pancreas powder (0350).*

Papain. *1150700.* [9001-73-4].

A proteolytic enzyme obtained from the latex of the green fruit and leaves of *Carica papaya* L.

Papaverine hydrochloride. *1061800.* [61-25-6].

See *Papaverine hydrochloride (0102).*

Paper chromatography performance test solutions. *1150800.*

Test solution (A). Sodium pertechnetate (^{99m}Tc) injection (fission) (0124) or *Sodium pertechnetate (^{99m}Tc) injection (non-fission) (0283).*

Test solution (B). In a closed vial mix 100 µL of a 5 g/L solution of *stannous chloride R* in *0.05 M hydrochloric acid* and 100 MBq to 200 MBq of *Sodium pertechnetate (^{99m}Tc) injection (fission) (0124)* or *Sodium pertechnetate (^{99m}Tc) injection (non-fission) (0283)* in a volume not exceeding 2 mL.

Paper for chromatography. *1150900.*

Pure cellulose grade thin paper with a smooth surface and a thickness of about 0.2 mm.

Chromatographic separation. To 2 strips of *paper for chromatography R* apply separately 2-5 µL of test solution (a) and test solution (b) of *paper chromatography performance test solutions R*. Develop over a pathlength of 3/4 of the paper height, using a mixture of equal volumes of *methanol R* and *water R*. Allow to dry and determine the distribution of radioactivity using a suitable detector. The paper is not satisfactory, unless the chromatogram obtained with test solution (a) shows a single radioactivity spot with an R_F value in the range 0.8-1.0 and the chromatogram obtained with test solution (b) shows a single radioactivity spot at the application point (R_F value in the range 0.0-0.1).

Paracetamol. *1061900.* [103-90-2].

See *Paracetamol (0049).*

Paracetamol, 4-aminophenol-free. *1061901.*

Recrystallise *paracetamol R* from *water R* and dry *in vacuo* at 70 °C; repeat the procedure until the product complies with the following test: dissolve 5 g of the dried substance in a mixture of equal volumes of *methanol R* and *water R* and dilute to 100 mL with the same mixture of solvents. Add 1 mL of a freshly prepared solution containing 10 g/L of *sodium nitroprusside R* and 10 g/L of *anhydrous sodium carbonate R*, mix and allow to stand for 30 min protected from light. No blue or green colour is produced.

Paraffin, liquid. *1062000.* [8042-47-5].

See *Liquid paraffin (0239).*

Paraffin, white soft. *1062100.*

A semi-liquid mixture of hydrocarbons obtained from petroleum and bleached, practically insoluble in water and in ethanol (96 per cent), soluble in *light petroleum R1*, the solution sometimes showing a slight opalescence.

Paraldehyde. *1151000.* [123-63-7].

See *Paraldehyde (0351).*

Pararosaniline hydrochloride. $C_{19}H_{18}ClN_3$. (M_r 323.8). *1062200.* [569-61-9].

Schultz No. 779.

Colour Index No. 42500.

4-[bis(4-Aminophenyl)methylene]cyclohexa-2,5-dieniminium chloride.

Bluish-red, crystalline powder, slightly soluble in water, soluble in anhydrous ethanol. Solutions in water and anhydrous ethanol are deep-red; solutions in sulfuric acid and in hydrochloric acid are yellow.

mp: about 270 °C, with decomposition.

Decolorised pararosaniline solution. *1062201.*

To 0.1 g of *pararosaniline hydrochloride R* in a ground-glass-stoppered flask add 60 mL of *water R* and a solution of 1.0 g of *anhydrous sodium sulfite R* or 2.0 g of *sodium sulfite R* or 0.75 g of *sodium metabisulfite R* in 10 mL of *water R*. Slowly and with stirring add 6 mL of *dilute hydrochloric acid R*, stopper the flask and continue stirring until dissolution is complete. Dilute to 100 mL with *water R*. Allow to stand for 12 h before use.

Storage: protected from light.

Parthenolide. $C_{15}H_{20}O_3$. (M_r 248.3). *1129900.* [20554-84-1]. (4*E*)-(1a*R*,7a*S*,10a*S*,10b*S*)-1a,5-Dimethyl-8-methylene-2,3,6,7,7a,8,10a,10b-octahydro-oxireno[9,10]cyclodeca[1,2-*b*]furan-9(1a*H*)-one. (*E*)-(5*S*,6*S*)-4,5-Epoxygermacra-1(10),11(13)-dieno-12(6)-lactone.

White or almost white, crystalline powder, very slightly soluble in water, very soluble in methylene chloride, soluble in methanol.

$[\alpha]_D^{22}$: −71.4, determined on a 2.2 g/L solution in *methylene chloride R*.

mp: 115 °C to 116 °C.

Absorbance (*2.2.25*). A 0.01 g/L solution in *ethanol (96 per cent) R* shows an absorption maximum at 214 nm.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Feverfew (1516)*, at the concentration of the reference solution.

Content: minimum 90 per cent, calculated by the normalisation procedure.

Penicillinase solution. *1062300.*

Dissolve 10 g of casein hydrolysate, 2.72 g of *potassium dihydrogen phosphate R* and 5.88 g of *sodium citrate R* in 200 mL of *water R*, adjust to pH 7.2 with a 200 g/L solution of *sodium hydroxide R* and dilute to 1000 mL with *water R*. Dissolve 0.41 g of *magnesium sulfate R* in 5 mL of *water R* and add 1 mL of a 1.6 g/L solution of *ferrous ammonium sulfate R* and sufficient *water R* to produce 10 mL. Sterilise both solutions by heating in an autoclave, cool, mix, distribute in shallow layers in conical flasks and inoculate with *Bacillus cereus* (NCTC 9946). Allow the flasks to stand at 18 °C to 37 °C until growth is apparent and then maintain at 35 °C to 37 °C for 16 h, shaking constantly to ensure maximum aeration. Centrifuge and sterilise the supernatant liquid by filtration through a membrane filter. 1.0 mL of penicillinase solution contains not less than 0.4 microkatals (corresponding to the hydrolysis of not less than 500 mg of benzylpenicillin to benzylpenicilloic acid per hour) at 30 °C and pH 7, provided that the concentration of benzylpenicillin does not fall below the level necessary for enzyme saturation.

The Michaelis constant for benzylpenicillin of the penicillinase in penicillinase solution is approximately 12 μg/mL.

Sterility (*2.6.1*). It complies with the test for sterility.

Storage: at a temperature between 0 °C and 2 °C for 2 to 3 days. When freeze-dried and kept in sealed ampoules, it may be stored for several months.

Pentaerythrityl tetrakis[3-(3,5-di(1,1-dimethylethyl)-4-hydroxyphenyl)propionate]. $C_{73}H_{108}O_{12}$. (M_r 1178). *1062400.* [6683-19-8]. Pentaerythrityl tetrakis[3-(3,5-di-*tert*-butyl-4-hydroxyphenyl) propionate]. 2,2′-bis(Hydroxymethyl)propane-1,3-diol tetrakis[3-[3,5-di(1,1-dimethylethyl)-4-hydroxyphenyl]]propionate.

White or slightly yellow, crystalline powder, practically insoluble in water, very soluble in acetone, soluble in methanol, slightly soluble in hexane.

mp: 110 °C to 125 °C.

α-form: 120 °C to 125 °C.

β-form: 110 °C to 115 °C.

Pentafluoropropanoic acid. $C_3HF_5O_2$. (M_r 164.0). *1151100.* [422-64-0].

Clear, colourless liquid.

d_{20}^{20}: about 1.561.

n_D^{20}: about 1.284.

bp: about 97 °C.

Pentafluoropropionic anhydride. $C_6F_{10}O_3$. (M_r 310.0). *1177300.* [356-42-3]. Pentafluoropropanoic anhydride.

Pentane. C_5H_{12}. (M_r 72.2). *1062500.* [109-66-0].

Clear, colourless, flammable liquid, very slightly soluble in water, miscible with acetone and with anhydrous ethanol.

d_{20}^{20}: about 0.63.

n_D^{20}: about 1.359.

bp: about 36 °C.

Pentane used in spectrophotometry complies with the following additional test.

Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 20 per cent at 200 nm, 50 per cent at 210 nm, 85 per cent at 220 nm, 93 per cent at 230 nm, 98 per cent at 240 nm.

1,2-Pentanediol. $C_5H_{12}O_2$. (M_r 104.2). *1155800.* [5343-92-0]. (2*RS*)-Pentane-1,2-diol.

d_4^{20}: about 0.971.

n_D^{20}: about 1.439.

bp: about 201 °C.

Pentanol. $C_5H_{12}O$. (M_r 88.1). *1062600.* [71-41-0]. 1-Pentanol.

Colourless liquid, sparingly soluble in water, miscible with ethanol (96 per cent).

n_D^{20}: about 1.410.

bp: about 137 °C.

3-Pentanone. $C_5H_{10}O$. (M_r 86.13). *1173600.* [96-22-0]. Diethyl ketone.

***tert*-Pentyl alcohol.** $C_5H_{12}O$. (M_r 88.1). *1062700.* [75-85-4]. *tert*-Amyl alcohol. 2-Methyl-2-butanol.

Volatile, flammable liquid, freely soluble in water, miscible with ethanol (96 per cent) and with glycerol.

d_{20}^{20}: about 0.81.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 100 °C and 104 °C.

Storage: protected from light.

Pepsin powder. *1062800.* [9001-75-6].

See *Pepsin powder (0682).*

Perchloric acid. $HClO_4$. (M_r 100.5). *1062900.* [7601-90-3].

Content: 70.0 per cent *m/m* to 73.0 per cent *m/m*.

Clear, colourless liquid, miscible with water.

d_{20}^{20}: about 1.7.

Assay. To 2.50 g add 50 mL of *water R* and titrate with *1 M sodium hydroxide*, using 0.1 mL of *methyl red solution R* as indicator.

1 mL of *1 M sodium hydroxide* is equivalent to 100.5 mg of $HClO_4$.

Perchloric acid solution. *1062901.*

Dilute 8.5 mL of *perchloric acid R* to 100 mL with *water R*.

Periodic acetic acid solution. *1063000.*

Dissolve 0.446 g of *sodium periodate R* in 2.5 mL of a 25 per cent *V/V* solution of *sulfuric acid R*. Dilute to 100.0 mL with *glacial acetic acid R*.

Periodic acid. H_5IO_6. (M_r 227.9). *1108900.* [10450-60-9].

Crystals, freely soluble in water and soluble in ethanol (96 per cent).

mp: about 122 °C.

Permethrin. $C_{21}H_{20}Cl_2O_3$. (M_r 391.3). *1130000.* [52645–1].

mp: 34 °C to 35 °C.

A suitable certified reference solution (10 ng/µL in cyclohexane) may be used.

Peroxide test strips. *1147800.*

Use commercial test strips with a suitable scale in the range from 0 ppm to 25 ppm peroxide.

Perylene. $C_{20}H_{12}$. (M_r 252.3). *1130100.* [198-55-0]. Dibenz(de,kl)anthracene.

Orange powder.

mp: about 279 °C.

Petroleum, light. *1063100.* [8032-32-4]. Petroleum ether 50-70 °C.

Clear, colourless, flammable liquid without fluorescence, practically insoluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: 0.661 to 0.664.

Distillation range (*2.2.11*): 50 °C to 70 °C.

Petroleum, light R1. *1063101.* Petroleum ether 40-60 °C.

Complies with the requirements prescribed for *light petroleum R*, with the following modifications.

d_{20}^{20}: 0.630 to 0.656.

Distillation range (*2.2.11*): 40 °C to 60 °C. It does not become cloudy at 0 °C.

Petroleum, light R2. *1063102.* Petroleum ether 30-40 °C.

Complies with the requirements prescribed for *light petroleum R*, with the following modifications.

d_{20}^{20}: 0.620 to 0.630.

Distillation range (*2.2.11*): 30 °C to 40 °C. It does not become cloudy at 0 °C.

Petroleum, light R3. *1063103.* Petroleum ether 100-120 °C.

Complies with the requirements prescribed for *light petroleum R*, with the following modifications.

d_{20}^{20}: about 0.720.

Distillation range (*2.2.11*): 100 °C to 120 °C.

Water (*2.5.12*): maximum 0.03 per cent.

Petroleum, light R4. *1063104.* Petroleum ether 80-100 °C.

Complies with the requirements prescribed for *light petroleum R*, with the following modifications.

d_{20}^{20}: about 0.70.

Distillation range (*2.2.11*): 80 °C to 100 °C.

pH indicator strip. *1178900.*

Plastic strip containing multiple segments of different dye-impregnated papers allowing visual determination of pH in the prescribed range by comparison with a master chart.

α-Phellandrene. $C_{10}H_{16}$. (M_r 136.2). *1130400.* [4221-98-1]. (*R*)-5-Isopropyl-2-methyl-cyclohexa-1,3-diene. (−)-p-Mentha-1,5-diene.

n_D^{20}: about 1.471.

bp: 171 °C to 174 °C.

α-Phellandrene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Eucalyptus oil (0390).*

Test solution. The substance to be examined.

Content: 95.0 per cent, calculated by the normalisation procedure.

Phenanthrene. $C_{14}H_{10}$. (M_r 178.2). *1063200.* [85-01-8].

White or almost white crystals, practically insoluble in water, sparingly soluble in ethanol (96 per cent).

mp: about 100 °C.

Phenanthroline hydrochloride. $C_{12}H_9ClN_2,H_2O$. (M_r 234.7). *1063300.* [3829-86-5]. 1,10-Phenanthroline hydrochloride monohydrate.

White or almost white, crystalline powder, freely soluble in water, soluble in ethanol (96 per cent).

mp: about 215 °C, with decomposition.

Phenazone. *1063400.* [60-80-0].

See *Phenazone (0421).*

Phenol. *1063500.* [108-95-2].

See *Phenol (0631).*

Phenolphthalein. $C_{20}H_{14}O_4$. (M_r 318.3). *1063700.* [77-09-8]. 3,3-bis(4-Hydroxyphenyl)-3*H*-isobenzofuran-1-one.

White or yellowish-white powder, practically insoluble in water, soluble in ethanol (96 per cent).

Phenolphthalein paper. *1063704.*

Immerse strips of filter paper for a few minutes in *phenolphthalein solution R*. Allow to dry.

Phenolphthalein solution. *1063702.*

Dissolve 0.1 g of *phenolphthalein R* in 80 mL of *ethanol (96 per cent) R* and dilute to 100 mL with *water R*.

Test for sensitivity. To 0.1 mL of the phenolphthalein solution add 100 mL of *carbon dioxide-free water R*. The solution is colourless. Not more than 0.2 mL of *0.02 M sodium hydroxide* is required to change the colour to pink.

Colour change: pH 8.2 (colourless) to pH 10.0 (red).

Phenolphthalein solution R1. *1063703.*

A 10 g/L solution in *ethanol (96 per cent) R*.

Phenol red. *1063600.* [143-74-8].

Bright red or dark red, crystalline powder, very slightly soluble in water, slightly soluble in ethanol (96 per cent).

Phenol red solution. *1063601.*

Dissolve 0.1 g of *phenol red R* in a mixture of 2.82 mL of *0.1 M sodium hydroxide* and 20 mL of *ethanol (96 per cent) R* and dilute to 100 mL with *water R*.

Test for sensitivity. Add 0.1 mL of the phenol red solution to 100 mL of *carbon dioxide-free water R*. The solution is yellow. Not more than 0.1 mL of *0.02 M sodium hydroxide* is required to change the colour to reddish-violet.

Colour change: pH 6.8 (yellow) to pH 8.4 (reddish-violet).

Phenol red solution R2. *1063603.*

Solution A. Dissolve 33 mg of *phenol red R* in 1.5 mL of *dilute sodium hydroxide solution R* and dilute to 100 mL with *water R*.

Solution B. Dissolve 25 mg of *ammonium sulfate R* in 235 mL of *water R*; add 105 mL of *dilute sodium hydroxide solution R* and 135 mL of *dilute acetic acid R*.

Add 25 mL of solution A to solution B. If necessary, adjust the pH of the mixture to 4.7.

Phenol red solution R3. *1063604.*

Solution A. Dissolve 33 mg of *phenol red R* in 1.5 mL of *dilute sodium hydroxide solution R* and dilute to 50 mL with *water R*.

Solution B. Dissolve 50 mg of *ammonium sulfate R* in 235 mL of *water R*; add 105 mL of *dilute sodium hydroxide solution R* and 135 mL of *dilute acetic acid R*.

Add 25 mL of solution A to solution B; if necessary, adjust the pH of the mixture to 4.7.

Phenoxyacetic acid. $C_8H_8O_3$. (M_r 152.1). *1063800.* [122-59-8]. 2-Phenoxyethanoic acid.

Almost white crystals, sparingly soluble in water, freely soluble in ethanol (96 per cent), and in glacial acetic acid.

mp: about 98 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Phenoxymethylpenicillin (0148)*; the chromatogram shows only one principal spot.

2-Phenoxyaniline. $C_{12}H_{11}NO$. (M_r 185.2). *1165500.* [2688-84-8]. 2-Phenoxybenzenamine. 2-Aminophenyl phenyl ether.

Phenoxybenzamine hydrochloride. $C_{18}H_{23}Cl_2NO$. (M_r 340.3). *1063900. N*-(2-Chloroethyl)-*N*-(1-methyl-2-phenoxyethyl)-benzylamine hydrochloride.

Content: 97.0 per cent to 103.0 per cent (dried substance).

White or almost white, crystalline powder, sparingly soluble in water, freely soluble in ethanol (96 per cent).

mp: about 138 °C.

Loss on drying (*2.2.32*): maximum 0.5 per cent, determined by drying over *diphosphorus pentoxide R* at a pressure not exceeding 670 Pa for 24 h.

Assay. Dissolve 0.500 g in 50.0 mL of *ethanol-free chloroform R* and extract with three quantities, each of 20 mL, of *0.01 M hydrochloric acid*. Discard the acid extracts, filter the chloroform layer through cotton and dilute 5.0 mL of the filtrate to 500.0 mL with *ethanol-free chloroform R*. Measure the absorbance of the resulting solution in a closed cell at the maximum at 272 nm. Calculate the content of $C_{18}H_{23}Cl_2NO$, taking the specific absorbance to be 56.3.

Storage: protected from light.

Phenoxyethanol. $C_8H_{10}O_2$. (M_r 138.2). *1064000.* [122-99-6]. 2-Phenoxyethanol.

Clear, colourless, oily liquid, slightly soluble in water, freely soluble in ethanol (96 per cent).

d_{20}^{20}: about 1.11.

n_D^{20}: about 1.537.

Freezing point (*2.2.18*): minimum 12 °C.

Phenylacetic acid. $C_8H_8O_2$. (M_r 136.2). *1160000.* [103-82-2].

White or almost white powder, soluble in water.

bp: about 265 °C.

mp: about 75 °C.

Phenylalanine. *1064100.* [63-91-2].

See *Phenylalanine (0782)*.

***p*-Phenylenediamine dihydrochloride.** $C_6H_{10}Cl_2N_2$. (M_r 181.1). *1064200.* [615-28-1]. 1,4-Diaminobenzene dihydrochloride.

Crystalline powder or white or slightly coloured crystals, turning reddish on exposure to air, freely soluble in water, slightly soluble in ethanol (96 per cent).

α-Phenylglycine. $C_8H_9NO_2$. (M_r 151.2). *1064300.* [2835-06-5]. (*RS*)-2-Amino-2-phenylacetic acid.

D-Phenylglycine. $C_8H_9NO_2$. (M_r 151.2). *1144500.* [875-74-1]. (2*R*)-2-Amino-2-phenylacetic acid.

Content: minimum 99 per cent.

White or almost white, crystalline powder.

Phenylhydrazine hydrochloride. $C_6H_9ClN_2$. (M_r 144.6). *1064500.* [59-88-1].

White or almost white, crystalline powder, becoming brown on exposure to air, soluble in water and in ethanol (96 per cent).

mp: about 245 °C, with decomposition.

Storage: protected from light.

Phenylhydrazine hydrochloride solution. *1064501.*

Dissolve 0.9 g of *phenylhydrazine hydrochloride R* in 50 mL of *water R*. Decolorise with *activated charcoal R* and filter. To the filtrate add 30 mL of *hydrochloric acid R* and dilute to 250 mL with *water R*.

Phenylhydrazine-sulfuric acid solution. *1064502.*

Dissolve 65 mg of *phenylhydrazine hydrochloride R*, previously recrystallised from *ethanol (85 per cent V/V) R*, in a mixture of 80 volumes of *water R* and 170 volumes of *sulfuric acid R* and dilute to 100 mL with the same mixture of solvents. Prepare immediately before use.

Phenyl isothiocyanate. C_7H_5NS. (M_r 135.2). *1121500.* [103-72-0].

Liquid, insoluble in water, soluble in ethanol (96 per cent).

d_{20}^{20}: about 1.13.

n_D^{20}: about 1.65.

bp: about 221 °C.

mp: about −21 °C.

Use a grade suitable for protein sequencing.

1-Phenylpiperazine. $C_{10}H_{14}N_2$. (M_r 162.2). *1130500.* [92-54-6].

Slightly viscous, yellow liquid, not miscible with water.

d_4^{20}: about 1.07.

n_D^{20}: about 1.588.

Phloroglucide. $C_{12}H_{10}O_5$. (M_r 234.2). *1177400.* [491-45-2]. 2,3′,4,5′,6-Biphenylpentol.

White or almost white powder, hygroscopic, light sensitive. Slowly discolours on exposure to light.

Phloroglucinol. $C_6H_6O_3,2H_2O$. (M_r 162.1). *1064600.* [6099-90-7]. Benzene-1,3,5-triol.

White or yellowish crystals, slightly soluble in water, soluble in ethanol (96 per cent).

mp: about 223 °C (instantaneous method).

Phloroglucinol solution. *1064601.*

To 1 mL of a 100 g/L solution of *phloroglucinol R* in *ethanol (96 per cent) R*, add 9 mL of *hydrochloric acid R*.

Storage: protected from light.

Phosalone. $C_{12}H_{15}ClNO_4PS_2$. (M_r 367.8). *1130200.* [2310-17-0].
mp: 45 °C to 48 °C
A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

Phosphomolybdic acid. $12MoO_3,H_3PO_4,xH_2O$. *1064900.* [51429-74-4].
Orange-yellow, fine crystals, freely soluble in water, soluble in ethanol (96 per cent).

Phosphomolybdic acid solution. *1064901.*
Dissolve 4 g of *phosphomolybdic acid R* in *water R* and dilute to 40 mL with the same solvent. Add cautiously and with cooling 60 mL of *sulfuric acid R*. Prepare immediately before use.

Phosphomolybdotungstic reagent. *1065000.*
Dissolve 100 g of *sodium tungstate R* and 25 g of *sodium molybdate R* in 700 mL of *water R*. Add 100 mL of *hydrochloric acid R* and 50 mL of *phosphoric acid R*. Heat the mixture under a reflux condenser in a glass apparatus for 10 h. Add 150 g of *lithium sulfate R*, 50 mL of *water R* and a few drops of *bromine R*. Boil to remove the excess of bromine (15 min), allow to cool, dilute to 1000 mL with *water R* and filter. The reagent should be yellow in colour. If it acquires a greenish tint, it is unsatisfactory for use but may be regenerated by boiling with a few drops of *bromine R*. Care must be taken to remove the excess of bromine by boiling.
Storage: at 2 °C to 8 °C.

Phosphomolybdotungstic reagent, dilute. *1065001.*
To 1 volume of *phosphomolybdotungstic reagent R* add 2 volumes of *water R*.

Phosphoric acid. *1065100.* [7664-38-2].
See *Concentrated phosphoric acid (0004).*

Phosphoric acid, dilute. *1065101.*
See *Dilute phosphoric acid (0005).*

Phosphoric acid, dilute R1. *1065102.*
Dilute 93 mL of *dilute phosphoric acid R* to 1000 mL with *water R*.

Phosphorous acid. H_3PO_3. (M_r 82.0). *1130600.* [13598-36-2].
White or almost white, very hygroscopic and deliquescent crystalline mass; slowly oxidised by oxygen (air) to H_3PO_4.
Unstable, orthorhombic crystals, soluble in water, in ethanol (96 per cent) and in a mixture of 3 volumes of ether and 1 volume of ethanol (96 per cent).
d_4^{21}: 1.651.
mp: about 73 °C.

Phosphotungstic acid solution. *1065200.*
Heat under a reflux condenser for 3 h, 10 g of *sodium tungstate R* with 8 mL of *phosphoric acid R* and 75 mL of *water R*. Allow to cool and dilute to 100 mL with *water R*.

Phthalaldehyde. $C_8H_6O_2$. (M_r 134.1). *1065300.* [643-79-8].
Benzene-1,2-dicarboxaldehyde.
Yellow, crystalline powder.
mp: about 55 °C.
Storage: protected from light and air.

Phthalaldehyde reagent. *1065301.*
Dissolve 2.47 g of *boric acid R* in 75 mL of *water R*, adjust to pH 10.4 using a 450 g/L solution of *potassium hydroxide R* and dilute to 100 mL with *water R*. Dissolve 1.0 g of *phthalaldehyde R* in 5 mL of *methanol R*, add 95 mL of the boric acid solution and 2 mL of *thioglycollic acid R* and adjust to pH 10.4 with a 450 g/L solution of *potassium hydroxide R*.
Storage: protected from light; use within 3 days.

Phthalazine. $C_8H_6N_2$. (M_r 130.1). *1065400.* [253-52-1].
Pale yellow crystals, freely soluble in water, soluble in anhydrous ethanol, in ethyl acetate and in methanol.
mp: 89 °C to 92 °C.

Phthalein purple. $C_{32}H_{32}N_2O_{12},xH_2O$. ($M_r$ 637, anhydrous substance). *1065500.* [2411-89-4]. Metalphthalein. 2,2′,2″,2‴-[*o*-Cresolphthalein-3′,3″-bis(methylenenitrilo)]tetra-acetic acid. (1,3-Dihydro-3-oxo-isobenzofuran-1-ylidene)bis[(6-hydroxy-5-methyl-3,1-phenylene)bis(methyleneimino)diacetic acid].
Yellowish-white or brownish powder, practically insoluble in water, soluble in ethanol (96 per cent). The product may be found in commerce in the form of the sodium salt: a yellowish-white to pink powder, soluble in water, practically insoluble in ethanol (96 per cent).
Test for sensitivity. Dissolve 10 mg in 1 mL of *concentrated ammonia R* and dilute to 100 mL with *water R*. To 5 mL of the solution add 95 mL of *water R*, 4 mL of *concentrated ammonia R*, 50 mL of *ethanol (96 per cent) R* and 0.1 mL of *0.1 M barium chloride*. The solution is blue-violet. Add 0.15 mL of *0.1 M sodium edetate*. The solution becomes colourless.

Phthalic acid. $C_8H_6O_4$. (M_r 166.1). *1065600.* [88-99-3].
Benzene-1,2-dicarboxylic acid.
White or almost white, crystalline powder, soluble in hot water and in ethanol (96 per cent).

Phthalic anhydride. $C_8H_4O_3$. (M_r 148.1). *1065700.* [85-44-9].
Isobenzofuran-1,3-dione.
Content: minimum 99.0 per cent.
White or almost white flakes.
mp: 130 °C to 132 °C.
Assay. Dissolve 2.000 g in 100 mL of *water R* and boil under a reflux condenser for 30 min. Cool and titrate with *1 M sodium hydroxide*, using *phenolphthalein solution R* as indicator.
1 mL of *1 M sodium hydroxide* is equivalent to 74.05 mg of $C_8H_4O_3$.

Phthalic anhydride solution. *1065701.*
Dissolve 42 g of *phthalic anhydride R* in 300 mL of *anhydrous pyridine R*. Allow to stand for 16 h.
Storage: protected from light; use within 1 week.

Picein. $C_{14}H_{18}O_7$. (M_r 298.3). *1130700.* [530-14-3].
1-[4-(β-D-Glucopyranosyloxy)phenyl]ethanone.
p-(Acetylphenyl)-β-D-glucopyranoside.
mp: 194 °C to 195 °C.

Picric acid. $C_6H_3N_3O_7$. (M_r 229.1). *1065800.* [88-89-1].
2,4,6-Trinitrophenol.
Yellow prisms or plates, soluble in water and in ethanol (96 per cent).
Storage: moistened with *water R*.

Picric acid solution. *1065801.*
A 10 g/L solution.

Picric acid solution R1. *1065802.*
Prepare 100 mL of a saturated solution of *picric acid R* and add 0.25 mL of *strong sodium hydroxide solution R*.

α-Pinene. $C_{10}H_{16}$. (M_r 136.2). *1130800.* [7785-70-8].
(1*R*,5*R*)-2,6,6-Trimethylbicyclo[3.1.1]hept-2-ene.
Liquid not miscible with water.
d_{20}^{20}: about 0.859.
n_D^{20}: about 1.466.
bp: 154 °C to 156 °C.
α-Pinene used in gas chromatography complies with the following additional test.
Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Bitter-orange-flower oil (1175).*
Test solution. The substance to be examined.

Content: minimum 99.0 per cent, calculated by the normalisation procedure.

β-Pinene. $C_{10}H_{16}$. (M_r 136.2). *1109000.* [127-91-3]. 6,6-Dimethyl-2-methylenebicyclo[3.1.1]heptane.

Colourless, oily liquid, odour reminiscent of turpentine, practically insoluble in water, miscible with ethanol (96 per cent).

β-Pinene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Bitter-orange-flower oil (1175).*

Test solution. The substance to be examined.

Content: minimum 95.0 per cent.

Piperazine hydrate. *1065900.* [142-63-2].

See *Piperazine hydrate (0425).*

Piperidine. $C_5H_{11}N$. (M_r 85.2). *1066000.* [110-89-4]. Hexahydropyridine.

Colourless to slightly yellow, alkaline liquid, miscible with water, with ethanol (96 per cent) and with light petroleum.

bp: about 106 °C.

Piperitone. $C_{10}H_{16}O$. (M_r 152.2). *1151200.* [89-81-6]. 6-Isopropyl-3-methyl-cyclohex-2-en-1-one.

Pirimiphos-ethyl. $C_{13}H_{24}N_3O_3PS$. (M_r 333.4). *1130300.* [23505-41-1].

mp: 15 °C to 18 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Plasma, platelet-poor. *1066100.*

Withdraw 45 mL of human blood into a 50 mL plastic syringe containing 5 mL of a sterile 38 g/L solution of *sodium citrate R*. Without delay, centrifuge at 1500 *g* at 4 °C for 30 min. Remove the upper two-thirds of the supernatant plasma using a plastic syringe and without delay centrifuge at 3500 *g* at 4 °C for 30 min. Remove the upper two-thirds of the liquid and freeze it rapidly in suitable amounts in plastic tubes at or below – 40 °C. Use plastic or silicone-treated equipment.

Plasma substrate. *1066200.*

Separate the plasma from human or bovine blood collected into one-ninth its volume of a 38 g/L solution of *sodium citrate R*, or into two-sevenths its volume of a solution containing 20 g/L of *disodium hydrogen citrate R* and 25 g/L of *glucose R*. With the former, prepare the substrate on the day of collection of the blood. With the latter, prepare within two days of collection of the blood.

Storage: at – 20 °C.

Plasma substrate R1. *1066201.*

Use water-repellent equipment (made from materials such as suitable plastics or suitably silicone-treated glass) for taking and handling blood.

Collect a suitable volume of blood from each of at least five sheep; a 285 mL volume of blood collected into 15 mL of anticoagulant solution is suitable but smaller volumes may be collected, taking the blood, either from a live animal or at the time of slaughter, using a needle attached to a suitable cannula which is long enough to reach the bottom of the collecting vessel. Discarding the first few millilitres and collecting only free-flowing blood, collect the blood in a sufficient quantity of an anticoagulant solution containing 8.7 g of *sodium citrate R* and 4 mg of *aprotinin R* per 100 mL of *water R* to give a final ratio of blood to anticoagulant solution of 19 to 1. During and immediately after collection, swirl the flask gently to ensure mixing but do not allow frothing to occur. When collection is complete, close the flask and cool to 10-15 °C. When cold, pool the contents of all the flasks with the exception of any that show obvious haemolysis or clots and keep the pooled blood at 10-15 °C.

As soon as possible and within 4 h of collection, centrifuge the pooled blood at 1000-2000 *g* at 10-15 °C for 30 min. Separate the supernatant liquid and centrifuge it at 5000 *g* for 30 min. (Faster centrifugation, for example 20 000 *g* for 30 min, may be used if necessary to clarify the plasma, but filtration procedures should not be used.) Separate the supernatant liquid and, without delay, mix thoroughly and distribute the plasma substrate into small stoppered containers in portions sufficient for a complete heparin assay (for example 10 mL to 30 mL). Without delay, rapidly cool to a temperature below – 70 °C (for example by immersing the containers into liquid nitrogen) and store at a temperature below – 30 °C.

The plasma is suitable for use as plasma substrate in the assay for heparin if, under the conditions of the assay, it gives a clotting time appropriate to the method of detection used and if it provides reproducible, steep log dose-response curves.

When required for use, thaw a portion of the plasma substrate in a water-bath at 37 °C, gently swirling until thawing is complete; once thawed it should be kept at 10-20 °C and used without delay. The thawed plasma substrate may be lightly centrifuged if necessary; filtration procedures should not be used.

Plasma substrate R2. *1066202.*

Prepare from human blood containing less than 1 per cent of the normal amount of factor IX. Collect the blood into one-ninth its volume of a 38 g/L solution of *sodium citrate R*.

Storage: in small amounts in plastic tubes at a temperature of – 30 °C or lower.

Plasma substrate R3. *1066203.*

Prepare from human blood containing less than 1 per cent of the normal amount of factor XI. Collect the blood into one-ninth its volume of a 38 g/L solution of *sodium citrate R*.

Storage: in small amounts in plastic tubes at a temperature of – 30 °C or lower.

Plasma substrate deficient in factor V. *1066300.*

Use preferably a plasma which is congenitally deficient, or prepare it as follows: separate the plasma from human blood collected into one tenth of its volume of a 13.4 g/L solution of *sodium oxalate R*. Incubate at 37 °C for 24 h to 36 h. The coagulation time determined by the method prescribed for *coagulation factor V solution R* should be 70 s to 100 s. If the coagulation time is less than 70 s, incubate again for 12 h to 24 h.

Storage: in small quantities at a temperature of – 20 °C or lower.

Plasminogen, human. *1109100.* [9001-91-6].

A substance present in blood that may be activated to plasmin, an enzyme that lyses fibrin in blood clots.

Plutonium-242 spiking solution. *1167400.*

Contains 50 Bq/L ^{242}Pu and a 134 g/L solution of *lanthanum chloride heptahydrate R* in a 284 g/L solution of *nitric acid R*.

Poly[(cyanopropyl)methylphenylmethylsiloxane]. *1066500.*

See *poly[(cyanopropyl)(methyl)][(phenyl)(methyl)]siloxane R.*

Poly[(cyanopropyl)(methyl)][(phenyl)(methyl)]siloxane. *1066500.*

Contains 25 per cent of cyanopropyl groups, 25 per cent of phenyl groups and 50 per cent of methyl groups. (Average relative molecular mass 8000).

A very viscous liquid (viscosity about 9000 mPa·s).

d_{25}^{25}: about 1.10.

n_D^{25}: about 1.502.

Poly[(cyanopropyl)(phenyl)][dimethyl]siloxane. *1114800.*

Stationary phase for gas chromatography.

Contains 6 per cent of (cyanopropyl)(phenyl) groups and 94 per cent of dimethyl groups.

Poly(cyanopropyl)(phenylmethyl)siloxane. *1066600.*

Stationary phase for gas chromatography.

Contains 90 per cent of cyanopropylgroups and 10 per cent of phenylmethyl groups.

Poly(cyanopropyl)(7)(phenyl)(7)(methyl)(86)siloxane. *1109200.*

Stationary phase for gas chromatography.

Polysiloxane substituted with 7 per cent of cyanopropyl groups, 7 per cent of phenyl groups and 86 per cent of dimethyl groups.

Poly(cyanopropylphenyl)(14)(methyl)(86)siloxane. *1173700.*

Stationary phase for chromatography.

Contains 14 per cent of cyanopropylphenyl groups and 86 per cent of methyl groups.

Poly(cyanopropyl)siloxane. *1066700.*

Polysiloxane substituted with 100 per cent of cyanopropyl groups.

Poly(dimethyl)(diphenyl)(divinyl)siloxane. *1100000.*

Stationary phase for gas chromatography.

Contains 94 per cent of methyl groups, 5 per cent of phenyl groups and 1 per cent of vinyl groups. SE54.

Poly(dimethyl)(diphenyl)siloxane. *1066900.*

Stationary phase for gas chromatography.

Contains 95 per cent of methyl groups and 5 per cent of phenyl groups. DB-5, SE52.

Poly(dimethyl)(diphenyl)siloxane, base-deactivated. *1176600.*

Base-deactivated stationary phase for gas chromatography specially designed for amine analysis.

Contains 95 per cent of methyl groups and 5 per cent of phenyl groups.

Poly(dimethyl)(75)(diphenyl)(25)siloxane. *1171500.*

Stationary phase for chromatography.

Contains 75 per cent of methyl groups and 25 per cent of phenyl groups.

Poly(dimethyl)(85)(diphenyl)(15)siloxane. *1154700.*

Stationary phase for chromatography.

Contains 85 per cent of methyl groups and 15 per cent of phenyl groups. PS086.

Poly(dimethyl)siloxane. *1066800.*

Silicone gum rubber (methyl). Organosilicon polymer with the appearance of a semi-liquid, colourless gum.

The intrinsic viscosity, determined as follows is about 115 $mL \cdot g^{-1}$. Weigh 1.5 g, 1 g and 0.3 g of the substance to be examined to the nearest 0.1 mg, into 100 mL volumetric flasks. Add 40-50 mL of *toluene R*, shake until the substance is completely dissolved and dilute to 100.0 mL with the same solvent. Determine the viscosity (*2.2.9*) of each solution. Determine the viscosity of *toluene R* under the same conditions. Reduce the concentration of each solution by half by diluting with *toluene R*. Determine the viscosity of these solutions.

c = concentration in grams per 100 mL,

t_1 = flow time of the solution to be examined,

t_2 = flow time of toluene,

η_1 = viscosity of the solution to be examined in millipascal seconds,

η_2 = viscosity of toluene in millipascal seconds,

d_1 = relative density of the solution to be examined,

d_2 = relative density of toluene.

To obtain the relative densities use the following data.

Concentration (g/100 mL)	Relative density (d_1)
0 - 0.5	1.000
0.5 - 1.25	1.001
1.25 - 2.20	1.002
2.20 - 2.75	1.003
2.75 - 3.20	1.004
3.20 - 3.75	1.005
3.75 - 4.50	1.006

The specific viscosity is obtained from the following equation:

$$\eta_{sp} = \frac{\eta_1 - \eta_2}{\eta_2} = \frac{t_1 d_1}{t_2 d_2} - 1$$

and the reduced viscosity from:

$$\eta_{red} = \frac{\eta_{sp}}{c}$$

The intrinsic viscosity (η) is obtained by extrapolating the preceding equation to $c = 0$. This is done by plotting the curve η_{sp}/c or $\log \eta_{sp}/c$ as a function of c. Extrapolation to $c = 0$ gives η. The intrinsic viscosity is expressed in millilitres per gram; the value obtained must therefore be multiplied by 100.

The infrared absorption spectrum (*2.2.24*) obtained by applying the substance, if necessary dispersed in a few drops of *carbon tetrachloride R*, to a sodium chloride plate, does not show absorption at 3053 cm^{-1}, corresponding to vinyl groups.

Loss on drying (*2.2.32*): maximum 2.0 per cent, determined on 1.000 g by drying *in vacuo* at 350 °C for 15 min; maximum 0.8 per cent, determined on 2.000 g by drying at 200 °C for 2 h.

Polyether hydroxylated gel for chromatography. *1067000.*

Gel with a small particle size having a hydrophilic surface with hydroxyl groups. It has an exclusion limit for dextran of relative molecular mass 2×10^5 to 2.5×10^6.

Polyethyleneglycol adipate. $(C_8H_{12}O_4)_n$. $(M_r\ (172.2)_n)$. *1067700.*

White or almost white, wax-like mass, practically insoluble in water.

mp: about 43 °C.

Polyethyleneglycol, base-deactivated. *1170300.*

Stationary phase for gas chromatography.

Cross-linked, base-deactivated polyethyleneglycol specially designed for amine analysis.

Polyethyleneglycol, polar-deactivated. *1179000.*

Stationary phase for gas chromatography.

Polyethyleneglycol succinate. $(C_6H_8O_4)_n$. $(M_r\ (144.1)_n)$. *1067800.*

White or almost white, crystalline powder, practically insoluble in water.

mp: about 102 °C.

Polymethacrylate gel, hydroxylated. *1151300.*

Stationary phase for size-exclusion chromatography.

Gel based on hydroxylated methacrylic acid polymer.

Polymethylphenylsiloxane. *1067900.*

Stationary phase for gas chromatography.

Contains 50 per cent of methyl groups and 50 per cent of phenyl groups. (Average relative molecular mass 4000).

Very viscous liquid (viscosity about 1300 mPa·s).

d_{25}^{25}: about 1.09.
n_D^{25}: about 1.540.

Poly[methyl(95)phenyl(5)]siloxane. *1068000.*
See *Poly(dimethyl)(diphenyl)siloxane R.*

Poly[methyl(94)phenyl(5)vinyl(1)]siloxane. *1068100.*
See *Poly(dimethyl)(diphenyl)(divinyl)siloxane R.*

Poly[methyl(trifluoropropylmethyl)siloxane]. *1171600.*
Stationary phase for gas chromatography.
Contains 50 per cent of trifluoropropylmethyl groups and 50 per cent of methyl groups.

Polyoxyethylated castor oil. *1068200.*
Light yellow liquid. It becomes clear above 26 °C.

Polysorbate 20. *1068300.* [9005-64-5].
See *Polysorbate 20 (0426).*

Polysorbate 80. *1068400.* [9005-65-6].
See *Polysorbate 80 (0428).*

Polystyrene 900-1000. *1112200.* [9003-53-6].
Organic standard used for calibration in gas chromatography.
M_w: about 950.
M_w/M_n: 1.10.

Potassium acetate. *1175900.* [127-08-2].
See *Potassium acetate (1139).*

Potassium bicarbonate. *1069900.* [298-14-6].
See *Potassium hydrogen carbonate R.*

Potassium bicarbonate solution, saturated methanolic. *1069901.*
See *potassium hydrogen carbonate solution, saturated methanolic R.*

Potassium bromate. $KBrO_3$. (M_r 167.0). *1068700.* [7758-01-2].
White or almost white granular powder or crystals, soluble in water, slightly soluble in ethanol (96 per cent).

Potassium bromide. *1068800.* [7758-02-3].
See *Potassium bromide (0184).*
Potassium bromide used for infrared absorption spectrophotometry (2.2.24) also complies with the following additional test.
A disc 2 mm thick prepared from the substance previously dried at 250 °C for 1 h, has a substantially flat baseline over the range 4000 cm^{-1} to 620 cm^{-1}. It exhibits no maxima with absorbance greater than 0.02 above the baseline, except maxima for water at 3440 cm^{-1} and 1630 cm^{-1}.

Potassium carbonate. K_2CO_3. (M_r 138.2). *1068900.* [584-08-7]. Dipotassium carbonate.
White or almost white, granular powder, hygroscopic, very soluble in water, practically insoluble in anhydrous ethanol.
Storage: in an airtight container.

Potassium chlorate. $KClO_3$. (M_r 122.6). *1069000.* [3811-04-9].
A white or almost white powder, granules or crystals, soluble in water.

Potassium chloride. *1069100.* [7447-40-7].
See *Potassium chloride (0185).*
Potassium chloride used for infrared absorption spectrophotometry (2.2.24) also complies with the following additional test.
A disc 2 mm thick, prepared from the substance previously dried at 250 °C for 1 h, has a substantially flat baseline over the range 4000 cm^{-1} to 620 cm^{-1}. It exhibits no maxima with absorbance greater than 0.02 above the baseline, except maxima for water at 3440 cm^{-1} and 1630 cm^{-1}.

Potassium chloride, 0.1 M. *1069101.*
A solution of *potassium chloride R* containing the equivalent of 7.46 g of KCl in 1000.0 mL.

Potassium chromate. K_2CrO_4. (M_r 194.2). *1069200.* [7789-00-6]. Dipotassium chromate.
Yellow crystals, freely soluble in water.

Potassium chromate solution. *1069201.*
A 50 g/L solution.

Potassium citrate. *1069300.* [6100-05-6].
See *Potassium citrate (0400).*

Potassium cyanide. KCN. (M_r 65.1). *1069400.* [151-50-8].
White or almost white, crystalline powder or white or almost white mass or granules, freely soluble in water, slightly soluble in ethanol (96 per cent).

Potassium cyanide solution. *1069401.*
A 100 g/L solution.

Potassium cyanide solution, lead-free. *1069402.*
Dissolve 10 g of *potassium cyanide R* in 90 mL of *water R*, add 2 mL of *strong hydrogen peroxide solution R* diluted 1 to 5. Allow to stand for 24 h, dilute to 100 mL with *water R* and filter.
The solution complies with the following test: take 10 mL of the solution, add 10 mL of *water R* and 10 mL of *hydrogen sulfide solution R*. No colour is evolved even after addition of 5 mL of *dilute hydrochloric acid R*.

Potassium dichromate. $K_2Cr_2O_7$. (M_r 294.2). *1069500.* [7778-50-9]. Dipotassium dichromate.
Potassium dichromate used for the calibration of spectrophotometers (*2.2.25*) contains not less than 99.9 per cent of $K_2Cr_2O_7$, calculated with reference to the substance dried at 130 °C.
Orange-red crystals, soluble in water, practically insoluble in ethanol (96 per cent).
Assay. Dissolve 1.000 g in *water R* and dilute to 250.0 mL with the same solvent. To 50.0 mL of this solution add a freshly prepared solution of 4 g of *potassium iodide R*, 2 g of *sodium hydrogen carbonate R* and 6 mL of *hydrochloric acid R* in 100 mL of *water R* in a 500 mL flask. Stopper the flask and allow to stand protected from light for 5 min. Titrate with *0.1 M sodium thiosulfate*, using 1 mL of *iodide-free starch solution R* as indicator.
1 mL of *0.1 M sodium thiosulfate* is equivalent to 4.903 mg of $K_2Cr_2O_7$.

Potassium dichromate solution. *1069501.*
A 106 g/L solution.

Potassium dichromate solution R1. *1069502.*
A 5 g/L solution.

Potassium dihydrogen phosphate. *1069600.* [7778-77-0].
See *Potassium dihydrogen phosphate (0920).*

Potassium dihydrogen phosphate, 0.2 M. *1069601.*
A solution of *potassium dihydrogen phosphate R* containing the equivalent of 27.22 g of KH_2PO_4 in 1000.0 mL.

Potassium ferricyanide. $K_3[Fe(CN)_6]$. (M_r 329.3). *1069700.* [13746-66-2]. Potassium hexacyanoferrate(III).
Red crystals, freely soluble in water.

Potassium ferricyanide solution. *1069701.*
Wash 5 g of *potassium ferricyanide R* with a little *water R*, dissolve and dilute to 100 mL with *water R*. Prepare immediately before use.

Potassium ferriperiodate solution. *1070801.*

Dissolve 1 g of *potassium periodate R* in 5 mL of a freshly prepared 120 g/L solution of *potassium hydroxide R*. Add 20 mL of *water R* and 1.5 mL of *ferric chloride solution R1*. Dilute to 50 mL with a freshly prepared 120 g/L solution of *potassium hydroxide R*.

Potassium ferrocyanide. $K_4[Fe(CN)_6],3H_2O$. (M_r 422.4). *1069800.* [14459-95-1]. Potassium hexacyanoferrate(II).

Transparent yellow crystals, freely soluble in water, practically insoluble in ethanol (96 per cent).

Potassium ferrocyanide solution. *1069801.*

A 53 g/L solution.

Potassium fluoride. KF. (M_r 58.1). *1137800.* [7789-23-3].

Colourless crystals or white or almost white crystalline powder, deliquescent, soluble in water, practically insoluble in ethanol (96 per cent).

Potassium hydrogen carbonate. $KHCO_3$. (M_r 100.1). *1069900.* [298-14-6]. Potassium bicarbonate.

Transparent, colourless crystals, freely soluble in water, practically insoluble in ethanol (96 per cent).

Potassium hydrogen carbonate solution, saturated methanolic. *1069901.*

Dissolve 0.1 g of *potassium hydrogen carbonate R* in 0.4 mL of *water R*, heating on water-bath. Add 25 mL of *methanol R* and swirl, keeping the solution on the water-bath until dissolution is complete. Use a freshly prepared solution.

Potassium hydrogen phthalate. $C_8H_5KO_4$. (M_r 204.2). *1070000.* [877-24-7]. Potassium hydrogen benzene-1,2-dicarboxylate.

White or almost white crystals, soluble in water, slightly soluble in ethanol (96 per cent).

Potassium hydrogen phthalate, 0.2 M. *1070001.*

A solution of *potassium hydrogen phthalate R* containing the equivalent of 40.84 g of $C_8H_5KO_4$ in 1000.0 mL.

Potassium hydrogen sulfate. $KHSO_4$. (M_r 136.2). *1070100.* [7646-93-7].

Colourless, transparent, hygroscopic crystals, freely soluble in water giving a strongly acid solution.

Storage: in an airtight container.

Potassium hydrogen tartrate. $C_4H_5KO_6$. (M_r 188.2). *1070200.* [868-14-4]. Potassium hydrogen (2*R*,3*R*)-2,3-dihydroxybutane-1,4-dioate.

White or almost white, crystalline powder or colourless, slightly opaque crystals, slightly soluble in water, soluble in boiling water, practically insoluble in ethanol (96 per cent).

Potassium hydroxide. *1070300.* [1310-58-3].

See *Potassium hydroxide (0840)*.

Potassium hydroxide, alcoholic, 2 M. *1070301.*

Dissolve 12 g of *potassium hydroxide R* in 10 mL of *water R* and dilute to 100 mL with *ethanol (96 per cent) R*.

Potassium hydroxide in alcohol (10 per cent *V/V*), 0.5 M. *1070302.*

Dissolve 28 g of *potassium hydroxide R* in 100 mL of *ethanol (96 per cent) R* and dilute to 1000 mL with *water R*.

Potassium hydroxide solution, alcoholic. *1070303.*

Dissolve 3 g of *potassium hydroxide R* in 5 mL of *water R* and dilute to 100 mL with *aldehyde-free alcohol R*. Decant the clear solution. The solution should be almost colourless.

Potassium hydroxide solution, alcoholic R1. *1070304.*

Dissolve 6.6 g of *potassium hydroxide R* in 50 mL of *water R* and dilute to 1000 mL with *anhydrous ethanol R*.

Potassium iodate. KIO_3. (M_r 214.0). *1070400.* [7758-05-6].

White or almost white, crystalline powder, soluble in water.

Potassium iodide. *1070500.* [7681-11-0].

See *Potassium iodide (0186)*.

Potassium iodide and starch solution. *1070501.*

Dissolve 0.75 g of *potassium iodide R* in 100 mL of *water R*. Heat to boiling and add whilst stirring a solution of 0.5 g of *soluble starch R* in 35 mL of *water R*. Boil for 2 min and allow to cool.

Test for sensitivity. A mixture of 15 mL of the potassium iodide and starch solution, 0.05 mL of *glacial acetic acid R* and 0.3 mL of *iodine solution R2* is blue.

Potassium iodide solution. *1070502.*

A 166 g/L solution.

Potassium iodide solution, iodinated. *1070503.*

Dissolve 2 g of *iodine R* and 4 g of *potassium iodide R* in 10 mL of *water R*. When solution is complete dilute to 100 mL with *water R*.

Potassium iodide solution, iodinated R1. *1070505.*

Dissolve 500 mg of *iodine R* and 1.5 g of *potassium iodide R* in *water R* and dilute to 25 mL with the same solvent.

Potassium iodide solution, saturated. *1070504.*

A saturated solution of *potassium iodide R* in *carbon dioxide-free water R*. Make sure the solution remains saturated as indicated by the presence of undissolved crystals.

Test by adding to 0.5 mL of the saturated potassium iodide solution 30 mL of a mixture of 2 volumes of *chloroform R* and 3 volumes of *glacial acetic acid R*, as well as 0.1 mL of *starch solution R* . Any blue colour formed should be discharged by the addition of 0.05 mL of *0.1 M sodium thiosulfate*.

Storage: protected from light.

Potassium iodobismuthate solution. *1070600.*

To 0.85 g of *bismuth subnitrate R* add 40 mL of *water R*, 10 mL of *glacial acetic acid R* and 20 mL of a 400 g/L solution of *potassium iodide R*.

Potassium iodobismuthate solution, dilute. *1070603.*

Dissolve 100 g of *tartaric acid R* in 500 mL of *water R* and add 50 mL of *potassium iodobismuthate solution R1*.

Storage: protected from light.

Potassium iodobismuthate solution R1. *1070601.*

Dissolve 100 g of *tartaric acid R* in 400 mL of *water R* and add 8.5 g of *bismuth subnitrate R*. Shake for 1 h, add 200 mL of a 400 g/L solution of *potassium iodide R* and shake well. Allow to stand for 24 h and filter.

Storage: protected from light.

Potassium iodobismuthate solution R2. *1070602.*

Stock solution. Suspend 1.7 g of *bismuth subnitrate R* and 20 g of *tartaric acid R* in 40 mL of *water R*. To the suspension add 40 mL of a 400 g/L solution of *potassium iodide R* and stir for 1 h. Filter. The solution may be kept for several days in brown bottles.

Spray solution. Mix immediately before use 5 mL of the stock solution with 15 mL of *water R*.

Potassium iodobismuthate solution R3. *1070604.*

Dissolve 0.17 g of *bismuth subnitrate R* in a mixture of 2 mL of *glacial acetic acid R* and 18 mL of *water R*. Add 4 g of *potassium iodide R*, 1 g of *iodine R* and dilute to 100 mL with *dilute sulfuric acid R*.

Potassium iodobismuthate solution R4. *1070605.*

Dissolve 1.7 g of *bismuth subnitrate R* in 20 mL of *glacial acetic acid R*. Add 80 mL of *distilled water R*, 100 mL of a 400 g/L solution of *potassium iodide R*, 200 mL of *glacial acetic acid R* and dilute to 1000 mL with *distilled water R*. Mix 2 volumes of this solution with 1 volume of a 200 g/L solution of *barium chloride R*.

Potassium iodobismuthate solution R5. *1070606.*

To 0.85 g of *bismuth subnitrate R* add 10 mL of *glacial acetic acid R* and gently heat until completely dissolved. Add 40 mL of *water R* and allow to cool. To 5 mL of this solution, add 5 mL of a 400 g/L solution of *potassium iodide R*, 20 mL of *glacial acetic acid R* and 70 mL of *water R*.

Potassium nitrate. KNO_3. (M_r 101.1). *1070700.* [7757-79-1].

Colourless crystals, very soluble in water.

Potassium periodate. KIO_4. (M_r 230.0). *1070800.* [7790-21-8].

White or almost white, crystalline powder or colourless crystals, soluble in water.

Potassium permanganate. *1070900.* [7722-64-7].

See *Potassium permanganate (0121)*.

Potassium permanganate and phosphoric acid solution. *1070901.*

Dissolve 3 g of *potassium permanganate R* in a mixture of 15 mL of *phosphoric acid R* and 70 mL of *water R*. Dilute to 100 mL with *water R*.

Potassium permanganate solution. *1070902.*

A 30 g/L solution.

Potassium perrhenate. $KReO_4$. (M_r 289.3). *1071000.* [10466-65-6].

White or almost white, crystalline powder, soluble in water, slightly soluble in ethanol (96 per cent), in methanol and in propylene glycol.

Potassium persulfate. $K_2S_2O_8$. (M_r 270.3). *1071100.* [7727-21-1]. Dipotassium peroxodisulfate.

Colourless crystals or white or almost white, crystalline powder, sparingly soluble in water, practically insoluble in ethanol (96 per cent). Aqueous solutions decompose at room temperature and more rapidly on warming.

Potassium plumbite solution. *1071200.*

Dissolve 1.7 g of *lead acetate R*, 3.4 g of *potassium citrate R* and 50 g of *potassium hydroxide R* in *water R* and dilute to 100 mL with the same solvent.

Potassium pyroantimonate. $KSb(OH)_6$. (M_r 262.9). *1071300.* [12208-13-8]. Potassium hexahydroxoantimoniate.

White or almost white, crystals or crystalline powder, sparingly soluble in water.

Potassium pyroantimonate solution. *1071301.*

Dissolve 2 g of *potassium pyroantimonate R* in 95 mL of hot *water R*. Cool quickly and add a solution containing 2.5 g of *potassium hydroxide R* in 50 mL of *water R* and 1 mL of *dilute sodium hydroxide solution R*. Allow to stand for 24 h, filter and dilute to 150 mL with *water R*.

Potassium tartrate. $C_4H_4K_2O_6,{}^1/_2H_2O$. (M_r 235.3). *1071400.* [921-53-9]. Dipotassium (2*R*,3*R*)-2,3-dihydroxybutane-1,4-dioate hemihydrate.

White or almost white, granular powder or crystals, very soluble in water, very slightly soluble in ethanol (96 per cent).

Potassium tetraiodomercurate solution. *1071500.*

Dissolve 1.35 g of *mercuric chloride R* in 50 mL of *water R*. Add 5 g of *potassium iodide R* and dilute to 100 mL with *water R*.

Potassium tetraiodomercurate solution, alkaline. *1071600.*

Dissolve 11 g of *potassium iodide R* and 15 g of *mercuric iodide R* in *water R* and dilute to 100 mL with the same solvent. Immediately before use, mix 1 volume of this solution with an equal volume of a 250 g/L solution of *sodium hydroxide R*.

Potassium tetroxalate. $C_4H_3KO_8,2H_2O$. (M_r 254.2). *1071700.* [6100-20-5].

White or almost white, crystalline powder, sparingly soluble in water, soluble in boiling water, slightly soluble in ethanol (96 per cent).

Potassium thiocyanate. KSCN. (M_r 97.2). *1071800.* [333-20-0].

Colourless crystals, deliquescent, very soluble in water and in ethanol (96 per cent).

Storage: in an airtight container.

Potassium thiocyanate solution. *1071801.*

A 97 g/L solution.

Povidone. *1068500.* [9003-39-8].

See *Povidone (0685)*.

Procaine hydrochloride. *1109400.*

See *Procaine hydrochloride (0050)*.

Proline. $C_5H_9NO_2$. (M_r 115.1). *1152200.* [147-85-3]. L-Proline. (*S*)-Pyrrolidine-2-carboxylic acid.

White or almost white, finely crystallised powder, freely soluble in water and in mineral acids, soluble in ethanol (96 per cent).

Content: minimum 99.0 per cent.

$[\alpha]_D^{22}$: −51 to −53, determined on a 50 g/L solution in *1 M hydrochloric acid*.

Propanol. C_3H_8O. (M_r 60.1). *1072000.* [71-23-8]. 1-Propanol.

Clear colourless liquid, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: about 0.802 to 0.806.

bp: about 97.2 °C.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 96 °C and 99 °C.

2-Propanol. C_3H_8O. (M_r 60.1). *1072100.* [67-63-0]. Isopropyl alcohol.

Clear, colourless, flammable liquid, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: about 0.785.

bp: 81 °C to 83 °C.

2-Propanol R1. *1072101.*

Complies with the requirements prescribed for *2-propanol R* with the following additional requirements.

n_D^{20}: about 1.378.

Water (*2.5.12*): maximum 0.05 per cent, determined on 10 g.

Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 25 per cent at 210 nm, 55 per cent at 220 nm, 75 per cent at 230 nm, 95 per cent at 250 nm, 98 per cent at 260 nm.

Propetamphos. $C_{10}H_{20}NO_4PS$. (M_r 281.3). *1130900.* [31218-83-4].

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

Propidium iodide. $C_{27}H_{34}I_2N_4$. (M_r 668.4). *1154200.* [25535-16-4]. 3,8-Diamino-5-[3(diethylmethylammonio)propyl]-6-phenylphenanthridinium diiodide.

Dark red solid.

Propionaldehyde. C_3H_6O. (M_r 58.1). *1072300.* [123-38-6]. Propanal.

Liquid freely soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.81.

n_D^{20}: about 1.365.

bp: about 49 °C.

mp: about – 81 °C.

Propionic acid. $C_3H_6O_2$. (M_r 74.1). *1072400.* [79-09-4].

Oily liquid, soluble in ethanol (96 per cent), miscible with water.

d_{20}^{20}: about 0.993.

n_D^{20}: about 1.387.

bp: about 141 °C.

mp: about – 21 °C.

Propionic anhydride. $C_6H_{10}O_3$. (M_r 130.1). *1072500.* [123-62-6].

Clear, colourless liquid, soluble in ethanol (96 per cent).

d_{20}^{20}: about 1.01.

bp: about 167 °C.

Propionic anhydride reagent. *1072501.*

Dissolve 1 g of *toluenesulfonic acid R* in 30 mL of *glacial acetic acid R*, add 5 mL of *propionic anhydride R* and allow to stand for at least 15 min before use.

Storage: use within 24 h.

Propyl acetate. $C_5H_{10}O_2$. (M_r 102.1). *1072600.* [109-60-4].

d_{20}^{20}: about 0.888.

bp: about 102 °C.

mp: about – 95 °C.

Propyl parahydroxybenzoate. *1072700.* [94-13-3].

See *Propyl parahydroxybenzoate (0431)*.

D-Prolyl-L-phenylalanyl-L-arginine 4-nitroanilide dihydrochloride. $C_{26}H_{36}Cl_2N_8O_5$. (M_r 612). *1072800.*

Propylene glycol. *1072900.* [57-55-6].

See *Propylene glycol (0430)*.

Propylene oxide. C_3H_6O. (M_r 58.1). *1121800.* [75-56-9].

Colourless liquid, miscible with ethanol (96 per cent).

Protamine sulfate. *1073000.* [53597-25-4 (salmine) 9007-31-2 (clupeine)].

See *Protamine sulfate (0569)*.

Protopine hydrochloride. $C_{20}H_{20}ClNO_5$. (M_r 389.8). *1163500.* [6164-47-2].

5-Methyl-4,6,7,14-tetrahydrobis[1,3]benzodioxolo[4,5-*c*:5′,6′-*g*]azecin-13(5*H*)-one hydrochloride.

Pteroic acid. $C_{14}H_{12}N_6O_3$. (M_r 312.3). *1144600.* [119-24-4]. 4-[[(2-Amino-4-oxo-1,4-dihydropteridin-6-yl)methyl]amino]benzoic acid.

Crystals, soluble in solutions of alkali hydroxides.

Pulegone. $C_{10}H_{16}O$. (M_r 152.2). *1073100.* [89-82-7]. (*R*)-2-Isopropylidene-5-methylcyclohexanone. (+)-*p*-Menth-4-en-3-one.

Oily, colourless liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_{15}^{20}: about 0.936.

n_D^{20}: 1.485 to 1.489.

bp: 222 °C to 224 °C.

Pulegone used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405)*.

Test solution. The substance to be examined.

Content: minimum 98.0 per cent, calculated by the normalisation procedure.

Putrescine. $C_4H_{12}N_2$. (M_r 88.15). *1137900.* [110-60-1]. 1,4-Butanediamine. Tetramethylenediamine.

Colourless oily liquid, very soluble in water. Strong piperidine-like odour.

bp: about 159 °C.

mp: about 23 °C.

Pyridin-2-amine. $C_5H_6N_2$. (M_r 94.1). *1073400.* [504-29-0]. 2-Aminopyridine.

Large crystals soluble in water and in ethanol (96 per cent).

bp: about 210 °C.

mp: about 58 °C.

Pyridine. C_5H_5N. (M_r 79.1). *1073200.* [110-86-1].

Clear, colourless liquid, hygroscopic, miscible with water and with ethanol (96 per cent).

bp: about 115 °C.

Storage: in an airtight container.

Pyridine, anhydrous. *1073300.*

Dry *pyridine R* over *anhydrous sodium carbonate R*. Filter and distil.

Water (*2.5.12*): maximum 0.01 per cent *m/m*.

Pyridinium hydrobromide perbromide. $C_5H_6Br_3N$. (M_r 319.8). *1166100.* [39416-48-3]. Pyridinium tribromide(1-).

Red crystals.

Pyridylazonaphthol. $C_{15}H_{11}N_3O$. (M_r 249.3). *1073500.* [85-85-8]. 1-(2-Pyridylazo)-2-naphthol.

Brick-red powder, practically insoluble in water, soluble in ethanol (96 per cent), in methanol and in hot dilute alkali solutions.

mp: about 138 °C.

Pyridylazonaphthol solution. *1073501.*

A 1 g/L solution in *anhydrous ethanol R*.

Test for sensitivity. To 50 mL of *water R* add 10 mL of *acetate buffer solution pH 4.4 R*, 0.10 mL of *0.02 M sodium edetate* and 0.25 mL of the pyridylazonaphthol solution. After addition of 0.15 mL of a 5 g/L solution of *copper sulfate R*, the colour changes from light yellow to violet.

4-(2-Pyridylazo)resorcinol monosodium salt. $C_{11}H_8N_3NaO_2$, H_2O. (M_r 255.2). *1131500.* [16593-81-0].

Orange crystalline powder.

Pyrocatechol. $C_6H_6O_2$. (M_r 110.1). *1073600.* [120-80-9]. Benzene-1,2-diol.

Colourless or slightly yellow crystals, soluble in water, in acetone and in ethanol (96 per cent).

mp: about 102 °C.

Storage: protected from light.

Pyrogallol. $C_6H_6O_3$. (M_r 126.1). *1073700.* [87-66-1]. Benzene-1,2,3-triol.

White or almost white crystals, becoming brownish on exposure to air and light, very soluble in water and in ethanol (96 per cent), slightly soluble in carbon disulfide. On exposure to air, aqueous solutions, and more rapidly alkaline solutions, become brown owing to the absorption of oxygen.

mp: about 131 °C.

Storage: protected from light.

Pyrogallol solution, alkaline. *1073701.*

Dissolve 0.5 g of *pyrogallol R* in 2 mL of *carbon dioxide-free water R*. Dissolve 12 g of *potassium hydroxide R* in 8 mL of *carbon dioxide-free water R*. Mix the two solutions immediately before use.

Pyrrolidine. C_4H_9N. (M_r 71.1). *1165000.* [123-75-1].

Content: minimum 99 per cent.

bp: 87 °C to 88 °C.

2-Pyrrolidone. C_4H_7NO. (M_r 85.1). *1138000.* [616-45-5]. Pyrrolidin-2-one.

Liquid above 25 °C, miscible with water, with anhydrous ethanol and with ethyl acetate.

d_4^{25}: 1.116.

Water (*2.5.12*): maximum 0.2 per cent determined on 2.00 g.

Assay. Gas chromatography (*2.2.28*): use the normalisation procedure.

Test solution. Dissolve 1.0 g in *methanol R* and dilute to 10.0 mL with the same solvent.

Column:

– *material*: glass;

– *size*: *l* = 30 m; Ø = 0.53 mm;

– *stationary phase*: *macrogol 20 000 R* (1.0 µm).

Carrier gas: *helium for chromatography R*.

Flow rate: adjusted so that the retention time of 2-pyrrolidone is about 10 min.

Split ratio: 1:20.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 1	80
	1 - 12	80 → 190
	12 - 32	190
Injection port		200

Detection: flame ionisation.

Injection: 1 µL of the test solution.

Content: minimum 98.0 per cent.

Pyruvic acid. $C_3H_4O_3$. (M_r 88.1). *1109300.* [127-17-3]. 2-Oxopropanoic acid.

Yellowish liquid, miscible with water and with anhydrous ethanol.

d_{20}^{20}: about 1.267.

n_D^{20}: about 1.413.

bp: about 165 °C.

Quercetin dihydrate. $C_{15}H_{10}O_7,2H_2O$. (M_r 338.2). *1138100.* 2-(3,4-Dihydroxyphenyl)-3,5,7-trihydroxy-4*H*-1-benzopyran-4-one.

Yellow crystals or yellowish powder, practically insoluble in water, soluble in acetone and in methanol.

Water (*2.5.12*): maximum 12.0 per cent, determined on 0.100 g.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Ginkgo leaf (1828)*.

Content:minimum 90 per cent (anhydrous substance) calculated by the normalisation procedure.

Storage: protected from light.

Quercitrin. $C_{21}H_{20}O_{11}$. (M_r 448.4). *1138200.* [522-12-3]. Quercetin 3-L-rhamnopyranoside. 3-[(6-Deoxy-α-L-mannopyranosyl)oxy]-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-4*H*-1-benzopyran-4-one. Quercitroside.

Yellow crystals, practically insoluble in cold water, soluble in ethanol (96 per cent).

mp: 176 °C to 179 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Goldenrod (1892)*: apply 20 µL of the solution; after spraying, the chromatogram shows a yellowish-brown fluorescent zone with an R_F of about 0.6.

Storage: at a temperature of 2 °C to 8 °C.

Quinaldine red. $C_{21}H_{23}IN_2$. (M_r 430.3). *1073800.* [117-92-0]. 2-[2-[4-(Dimethylamino)phenyl]ethenyl]-1-ethylquinolinium iodide.

Dark bluish-black powder, sparingly soluble in water, freely soluble in ethanol (96 per cent).

Quinaldine red solution. *1073801.*

Dissolve 0.1 g of *quinaldine red R* in *methanol R* and dilute to 100 mL with the same solvent.

Colour change: pH 1.4 (colourless) to pH 3.2 (red).

Quinhydrone. $C_{12}H_{10}O_4$. (M_r 218.2). *1073900.* [106-34-3]. Equimolecular compound of 1,4-benzoquinone and hydroquinone.

Dark green, lustrous crystals or a crystalline powder, slightly soluble in water, sparingly soluble in hot water, soluble in ethanol (96 per cent) and in concentrated ammonia.

mp: about 170 °C.

Quinidine. $C_{20}H_{24}N_2O_2$. (M_r 324.4). *1074000.* [56-54-2]. (*S*)-(6-Methoxyquinol-4-yl)[(2*R*,4*S*,5*R*)-5-vinylquinuclidin-2-yl]methanol.

White or almost white crystals, very slightly soluble in water, sparingly soluble in ethanol (96 per cent), slightly soluble in methanol.

$[\alpha]_D^{20}$: about + 260, determined on a 10 g/L solution in *anhydrous ethanol R*.

mp: about 172 °C.

Storage: protected from light.

Quinidine sulfate. *1109500.* [6591-63-5].

See *Quinidine sulfate (0017)*.

Quinine. $C_{20}H_{24}N_2O_2$. (M_r 324.4). *1074100.* [130-95-0]. (*R*)-(6-Methoxyquinol-4-yl)[(2*S*,4*S*,5*R*)-5-vinylquinuclidin-2-yl]methanol.

White or almost white, microcrystalline powder, very slightly soluble in water, slightly soluble in boiling water, very soluble in anhydrous ethanol.

$[\alpha]_D^{20}$: about – 167, determined on a 10 g/L solution in *anhydrous ethanol R*.

mp: about 175 °C.

Storage: protected from light.

Quinine hydrochloride. *1074200.* [6119-47-7].

See *Quinine hydrochloride (0018)*.

Quinine sulfate. *1074300.* [6119-70-6].

See *Quinine sulfate (0019)*.

Rabbit erythrocyte suspension. *1074500.*

Prepare a 1.6 per cent *V/V* suspension of rabbit erythrocytes as follows: defibrinate 15 mL of freshly drawn rabbit blood by shaking with glass beads, centrifuge at 2000 *g* for 10 min and wash the erythrocytes with three quantities, each of 30 mL, of a 9 g/L solution of *sodium chloride R*. Dilute 1.6 mL of the suspension of erythrocytes to 100 mL with a mixture of 1 volume of *phosphate buffer solution pH 7.2 R* and 9 volumes of a 9 g/L solution of *sodium chloride R*.

Raclopride tartrate. $C_{19}H_{26}Cl_2N_2O_9$. (M_r 497.3). *1144700.* [98185-20-7]. Raclopride L-tartrate.

White or almost white solid, sensitive to light, soluble in water.

$[\alpha]_D^{25}$: + 0.3, determined on a 3 g/L solution.

mp: about 141 °C.

Rapeseed oil. *1074600.*

See *Rapeseed oil, refined (1369)*.

Reducing mixture. *1074700.*

Grind the substances added in the following order to obtain a homogeneous mixture: 20 mg of *potassium bromide R*, 0.5 g of *hydrazine sulfate R* and 5 g of *sodium chloride R*.

Reichstein's substance S. $C_{21}H_{30}O_4$. (M_r 346.5). *1175400.* [152-58-9].

Content: minimum 95.0 per cent.

mp: about 208 °C.

Resin for reversed-phase ion chromatography. *1131100.*

A neutral, macroporous, high specific surface area with a non-polar character resin consisting of polymer lattice of polystyrene cross-linked with divinylbenzene.

Resin, weak cationic. *1096000.*

See *weak cationic resin R*.

Resorcinol. *1074800.* [108-46-3].

See *Resorcinol (0290)*.

Resorcinol reagent. *1074801.*

To 80 mL of *hydrochloric acid R1* add 10 mL of a 20 g/L solution of *resorcinol R* and 0.25 mL of a 25 g/L solution of *copper sulfate R* and dilute to 100.0 mL with *water R*. Prepare the solution at least 4 h before use.

Storage: at 2 °C to 8 °C for 1 week.

Rhamnose. $C_6H_{12}O_5,H_2O$. (M_r 182.2). *1074900.* [6155-35-7]. L-(+)-Rhamnose. 6-Deoxy-L-mannose.

White or almost white, crystalline powder, freely soluble in water.

$[\alpha]_D^{20}$: + 7.8 to + 8.3, determined on a 50 g/L solution in *water R* containing about 0.05 per cent of NH_3.

Rhaponticin. $C_{21}H_{24}O_9$. (M_r 420.4). *1075000.* [155-58-8]. 3-Hydroxy-5-[2-(3-hydroxy-4-methoxyphenyl)ethenyl]phenyl β-D-glucopyranoside.

Yellowish-grey, crystalline powder, soluble in ethanol (96 per cent) and in methanol.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Rhubarb (0291)*; the chromatogram shows only one principal spot.

Rhodamine 6 G. $C_{28}H_{31}ClN_2O_3$. (M_r 479.0). *1153300.* [989-38-8].

Colour Index No. 45160.

9-[2-(Ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthenylium chloride.

Brownish-red powder.

Rhodamine B. $C_{28}H_{31}ClN_2O_3$. (M_r 479.0). *1075100.* [81-88-9].

Schultz No. 864.

Colour Index No. 45170.

[9-(2-Carboxyphen-yl)-6-(diethylamino)-3*H*-xanthen-3-ylidene]diethylammonium chloride.

Green crystals or reddish-violet powder, very soluble in water and in ethanol (96 per cent).

Ribose. $C_5H_{10}O_5$. (M_r 150.1). *1109600.* [50-69-1]. D-Ribose.

Soluble in water, slightly soluble in ethanol (96 per cent).

mp: 88 °C to 92 °C.

Ricinoleic acid. $C_{18}H_{34}O_3$. (M_r 298.5). *1100100.* [141-22-0]. 12-Hydroxyoleic acid.

Yellow or yellowish-brown viscous liquid, consisting of a mixture of fatty acids obtained by the hydrolysis of castor oil, practically insoluble in water, very soluble in anhydrous ethanol.

d_{20}^{20}: about 0.942.

n_D^{20}: about 1.472.

mp: about 285 °C, with decomposition.

Rosmarinic acid. $C_{18}H_{16}O_8$. (M_r 360.3). *1138300.* [20283-92-5].

mp: 170 °C to 174 °C.

Ruthenium red. $[(NH_3)_5RuORu(NH_3)_4ORu(NH_3)_5]Cl_6,4H_2O$. ($M_r$ 858). *1075200.* [11103-72-3].

Brownish-red powder, soluble in water.

Ruthenium red solution. *1075201.*

A 0.8 g/L solution in *lead acetate solution R*.

Rutin. $C_{27}H_{30}O_{16},3H_2O$. (M_r 665). *1075300.* [153-18-4]. Rutoside. 3-(*O*-6-Deoxy-α-L-mannopyranosyl-(1→6)-β-D-glucopyranosyloxy)-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-4*H*-chromen-4-one.

Yellow, crystalline powder, darkening in light, very slightly soluble in water, soluble in about 400 parts of boiling water, slightly soluble in ethanol (96 per cent), soluble in solutions of the alkali hydroxides and in ammonia.

mp: about 210 °C, with decomposition.

Absorbance (*2.2.25*). A solution in *ethanol (96 per cent) R* shows two absorption maxima at 259 nm and 362 nm.

Storage: protected from light.

Sabinene. $C_{10}H_{16}$. (M_r 136.2). *1109700.* [3387-41-5]. Thuj-4(10)-ene. 4-Methylene-1-isopropylbicyclo[3.1.0]hexane.

A colourless, oily liquid.

Sabinene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Bitter-orange-flower oil (1175)*.

Test solution. The substance to be examined.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Saccharin sodium. *1131400.* [128-44-9].

See *Saccharin sodium (0787)*.

Safrole. $C_{10}H_{10}O_2$. (M_r 162.2). *1131200.* [94-59-7]. 5-(Prop-2-enyl)-1,3-benzodioxole. 4-Allyl-1,2-(methylenedioxy)benzene.

Colourless or slightly yellow, oily liquid, with the odour of sassafras, insoluble in water, very soluble in ethanol (96 per cent), miscible with hexane.

d_{20}^{20}: 1.095 to 1.096.

n_D^{20}: 1.537 to 1.538.

bp: 232 °C to 234 °C.

Freezing point: about 11 °C.

Safrole used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Cinnamon bark oil, Ceylon (1501)*.

Content: minimum 96.0 per cent, calculated by the normalisation procedure.

Salicin. $C_{13}H_{18}O_7$. (M_r 286.3). *1131300.* [138-52-3]. 2-(Hydroxymethyl)phenyl-β-D-glucopyranoside. Salicoside.

$[\alpha]_D^{20}$: – 62.5 ± 2.

mp: 199 °C to 201 °C.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Willow bark (1583)* at the concentration of the reference solution.

Content: minimum 99.0 per cent, calculated by the normalisation procedure.

Salicylaldehyde. $C_7H_6O_2$. (M_r 122.1). *1075400.* [90-02-8]. 2-Hydroxybenzaldehyde.

Clear, colourless, oily liquid.

d_{20}^{20}: about 1.167.

n_D^{20}: about 1.574.

bp: about 196 °C.

mp: about – 7 °C.

Salicylaldehyde azine. $C_{14}H_{12}N_2O_2$. (M_r 240.3). *1075500.* [959-36-4]. 2,2′-Azinodimethyldiphenol.

Dissolve 0.30 g of *hydrazine sulfate R* in 5 mL of *water R*, add 1 mL of *glacial acetic acid R* and 2 mL of a freshly prepared 20 per cent *V/V* solution of *salicylaldehyde R* in *2-propanol R*. Mix, allow to stand until a yellow precipate is formed. Shake

with two quantities, each of 15 mL, of *methylene chloride R*. Combine the organic layers and dry over *anhydrous sodium sulfate R*. Decant or filter the solution and evaporate to dryness. Recrystallise from a mixture of 40 volumes of *methanol R* and 60 volumes of *toluene R* with cooling. Dry the crystals *in vacuo*.

mp: about 213 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the test for hydrazine in the monograph *Povidone (0685)*; the chromatogram shows only one principal spot.

Salicylic acid. *1075600.* [69-72-7].

See *Salicylic acid (0366).*

Sand. *1075800.*

White or slightly greyish grains of silica with a particle size between 150 µm and 300 µm.

Schisandrin. $C_{24}H_{32}O_7$. (M_r 432.5). *1173800.* [7432-28-2]. Schisandrol A. Wuweizichun A. (6*S*,7*S*,12a*R*$_a$)-5,6,7,8-Tetrahydro-1,2,3,10,11,12-hexamethoxy-6,7-dimethyldibenzo[*a*,*c*]cyclooctan-6-ol.

White or almost white, crystalline powder.

Schisandrin used in the assay in the monograph *Schisandra fruit (2428)* complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Schisandra fruit (2428).*

Content: minimum 95 per cent, calculated by the normalisation procedure.

Storage: in an airtight container, at – 20 °C or below.

γ-Schisandrin. $C_{23}H_{28}O_6$. (M_r 400.5). *1173900.* [61281-37-6]. Schisandrin B. Wuweizisu B. *rac*-(6*R*,7*S*,13a*R*$_a$)-1,2,3,13-Tetramethoxy-6,7-dimethyl-5,6,7,8-tetrahydrobenzo[3,4]cycloocta[1,2-*f*][1,3]benzodioxole.

White or almost white, crystalline powder.

Storage: in an airtight container, at – 20 °C or below.

Sclareol. $C_{20}H_{36}O_2$. (M_r 308.5). *1139900.* [515-03-7]. (1*R*,2*R*,4a*S*,8a*S*)-1-[(3*R*)-3-Hydroxy-3-methylpent-4-enyl]-2,5,5,8a-tetramethyldecahydronaphthalen-2-ol.

Odourless crystals.

$[\alpha]_D^{20}$: 6.7, determined with a solution in anhydrous ethanol.

$bp_{19\ mm}$: 218 °C to 220 °C.

mp: 96 °C to 98 °C.

Sclareol used in the chromatographic profile test in the monograph Clary sage oil (1850) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Clary sage oil (1850).*

Content: minimum 97 per cent, calculated by the normalisation procedure.

Scopoletin. $C_{10}H_8O_4$. (M_r 192.2). *1158700.* [92-61-5]. 7-Hydroxy-6-methoxy-2*H*-1-benzopyran-2-one. 7-Hydroxy-6-methoxycoumarin.

Faintly beige, fine crystals.

mp: 202 °C to 208 °C.

SDS-PAGE running buffer. *1114900.*

Dissolve 151.4 g of *tris(hydroxymethyl)aminomethane R*, 721.0 g of *glycine R* and 50.0 g of *sodium lauryl sulfate R* in *water R* and dilute to 5000 mL with the same solvent. Immediately before use, dilute to 10 times its volume with *water R* and mix. Measure the pH (*2.2.3*) of the diluted solution. The pH is between 8.1 and 8.8.

SDS-PAGE sample buffer (concentrated). *1115000.*

Dissolve 1.89 g of *tris(hydroxymethyl)aminomethane R*, 5.0 g of *sodium lauryl sulfate R* and 50 mg of *bromophenol blue R* in *water R*. Add 25.0 mL of *glycerol R* and dilute to 100 mL with *water R*. Adjust the pH to 6.8 with *hydrochloric acid R*, and dilute to 125 mL with *water R*.

SDS-PAGE sample buffer for reducing conditions (concentrated). *1122100.*

Dissolve 3.78 g of *tris(hydroxymethyl)aminomethane R*, 10.0 g of *sodium dodecyl sulfate R* and 100 mg of *bromophenol blue R* in *water R*. Add 50.0 mL of *glycerol R* and dilute to 200 mL with *water R*. Add 25.0 mL of *2-mercaptoethanol R*. Adjust to pH 6.8 with *hydrochloric acid R*, and dilute to 250.0 mL with *water R*.

Alternatively, dithiothreitol may be used as reducing agent instead of 2-mercaptoethanol. In this case prepare the sample buffer as follows: dissolve 3.78 g of *tris(hydroxymethyl)aminomethane R*, 10.0 g of *sodium dodecyl sulfate R* and 100 mg of *bromophenol blue R* in *water R*. Add 50.0 mL of *glycerol R* and dilute to 200 mL with *water R*. Adjust to pH 6.8 with *hydrochloric acid R*, and dilute to 250.0 mL with *water R*. Immediately before use, add *dithiothreitol R* to a final concentration of 100 mM.

Selenious acid. H_2SeO_3. (M_r 129.0). *1100200.* [7783-00-8].

Deliquescent crystals, freely soluble in water.

Storage: in an airtight container.

Selenium. Se. (A_r 79.0). *1075900.* [7782-49-2].

Brown-red or black powder or granules, practically insoluble in water and in ethanol (96 per cent), soluble in nitric acid.

mp: about 220 °C.

Serine. *1076000.* [56-45-1].

See *Serine (0788).*

Sialic acid. *1001100.* [131-48-6].

See *N-acetylneuraminic acid R.*

Silibinin. $C_{25}H_{22}O_{10}$. (M_r 482.4). *1151400.* [22888-70-6]. Silybin. (2*R*,3*R*)-3,5,7-Trihydroxy-2-[(2*R*,3*R*)-3-(4-hydroxy-3-methoxyphenyl)-2-(hydroxymethyl)-2,3-dihydro-1,4-benzodioxin-6-yl]-2,3-dihydro-4*H*-1-benzopyran-4-one.

White or yellowish powder, practically insoluble in water, soluble in acetone and in methanol.

Silibinin used in the assay of Milk-thistle fruit (1860) complies with the following additional test.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Milk-thistle fruit (1860).*

Test solution. Dissolve 5.0 mg of silibinin, dried *in vacuo*, in *methanol R* and dilute to 50.0 mL with the same solvent.

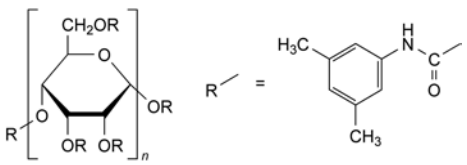
Silibinin A and silibinin B content: minimum 95.0 per cent, calculated by the normalisation procedure.

Silica gel π-acceptor/π-donor for chiral separations. *1160100.*

A very finely divided silica gel for chromatography consisting of spherical particles to which 1-(3,5-dinitrobenzamido)-1,2,3,4-tetrahydrophenantrene has been covalently bound, showing both π-electron acceptor and π-electron donor characteristics. The particle size and the configuration are indicated after the name of the reagent in the tests where it is used.

Silica gel AD for chiral separation. *1171700.*

A very finely divided silica gel for chromatography (5 µm) coated with the following derivative:



Silica gel AGP for chiral chromatography. *1148700.*

A very finely divided silica gel for chromatography consisting of spherical particles coated with α1- acid glycoprotein. The particle size is indicated after the name of the reagent in the tests where it is used.

Silica gel, anhydrous. *1076100* . [112926-00-8].

Partly dehydrated polymerised, amorphous silicic acid, absorbing at 20 °C about 30 per cent of its mass of water. Practically insoluble in water, partly soluble in solutions of sodium hydroxide. It contains a suitable indicator for detection of the humidity status, for which the colour change from the hydrated to anhydrous form is given on the label.

Silica gel BC for chiral chromatography. *1161300.*

A very finely divided silica gel for chromatography (5 µm) coated with β-cyclodextrin. Higher selectivity may be obtained when cyclodextrin has been derivatized with propylene oxide.

Silica gel for chromatography. *1076900.*

A very finely divided (3 µm-10 µm) silica gel. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, alkyl-bonded for use with highly aqueous mobile phases. *1160200.*

A very finely divided silica gel with bonded alkyl groups suitable for use with highly aqueous mobile phases.

Silica gel for chromatography, alkyl-bonded for use with highly aqueous mobile phases, end-capped. *1176900.*

A very finely divided silica gel with bonded alkyl groups suitable for use with highly aqueous mobile phases. To minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Silica gel for chromatography, amidohexadecylsilyl. *1170400.*

A very finely divided silica gel with a fine particle size, chemically modified at the surface by the bonding of amidohexadecylsilyl groups. The particle size is indicated after the name of the reagent in the test where it is used.

Silica gel for chromatography, aminohexadecylsilyl. *1138400.*

A very finely divided (3-10 µm) silica gel with a fine particle size chemically modified at the surface by the bonding of aminohexadecylsilyl groups. The particle size is indicated after the name of the reagent in the test where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, aminopropylmethylsilyl. *1102400.*

Silica gel with a fine particle size (between 3 µm and 10 µm), chemically modified by bonding aminopropylmethylsilyl groups on the surface. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, aminopropylsilyl. *1077000.*

Silica gel with a fine particle size (between 3 µm and 10 µm), chemically modified by bonding aminopropylsilyl groups on the surface. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, amylose derivative of. *1109800.*

A very finely divided (10 µm) silica gel, chemically modified at the surface by the bonding of an amylose derivative. The particle size is indicated after the name of the reagent in the test where it is used.

Fine, white or almost white, homogenous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, butylsilyl. *1076200.*

A very finely divided silica gel (3 µm-10 µm), chemically modified at the surface by the bonding of butylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Spheroidal silica: 30 nm.

Pore volume: 0.6 cm^3/g.

Specific surface area: 80 m^2/g.

Silica gel for chromatography, butylsilyl, end-capped. *1170500.*

A very finely divided silica (3-10 µm), chemically modified at the surface by the bonding of butylsilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogenous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, crown-ether. *1178000.*

Stationary phase for liquid chromatography.

Crown ether coated on silica gel.

Silica gel for chromatography, cyanosilyl. *1109900.*

A very finely divided silica gel chemically modified at the surface by the bonding of cyanosilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, di-isobutyloctadecylsilyl. *1140000.*

A very finely divided silica gel chemically modified at the surface by the bonding of di-isobutyloctadecylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Silica gel for chromatography, diisopropylcyanopropylsilyl. *1168100.*

A very finely divided silica gel chemically modified at the surface by the bonding of diisopropylcyanopropylsilyl groups. The particle size is indicated after the name of the reagent in which the test is used.

Silica gel for chromatography, dimethyloctadecylsilyl. *1115100.*

A very finely divided silica gel (3 µm-10 µm), chemically modified at the surface by the bonding of dimethyloctadecylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent). Irregular particle size.

Specific surface area: 300 m^2/g.

Silica gel for chromatography, diol. *1110000.*

Spherical silica particles to which dihydroxypropyl groups are bonded. Pore size 10 nm.

Silica gel for chromatography, hexadecylamidylsilyl. *1162500.*

A very finely divided (5 µm) silica gel, chemically modified at the surface by the introduction of hexadecylcarboxamidopropyldimethylsilyl groups.

Silica gel for chromatography, hexadecylamidylsilyl, end-capped. *1172400.*

A very finely divided (5 µm) silica gel, chemically modified at the surface by the introduction of hexadecylcarboxamidopropyldimethylsilyl groups. To minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups.

Silica gel for chromatography, hexylsilyl. *1077100.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of hexylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, hexylsilyl, end-capped. *1174400.*

A very finely divided (3-10 µm) silica gel, chemically modified at the surface by the bonding of hexylsilyl groups. To minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

A fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, human albumin coated. *1138500.*

A very finely divided (3 µm to 10 µm) silica gel, chemically modified at the surface by the bonding of human albumin. The particle size is indicated after the name of the reagent in the tests where it is used.

White or almost white, fine, homogeneous powder.

Silica gel for chromatography, hydrophilic. *1077200.*

A very finely divided (3 µm-10 µm) silica gel whose surface has been modified to provide hydrophilic characteristics. The particle size may be stated after the name of the reagent in the tests where it is used.

Silica gel for chromatography, nitrile. *1077300.*

A very finely divided silica gel, chemically modified at the surface by the bonding of cyanopropylsilyl groups. The particle size is indicated after the name of the reagent in the test where it is used.

Fine white or almost white, homogenous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, nitrile R1. *1077400.*

A very finely divided silica gel consisting of porous, spherical particles with chemically bonded nitrile groups. The particle size is indicated after the name of the reagent in the test where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, nitrile R2. *1119500.*

Ultrapure silica gel, chemically modified at the surface by the introduction of cyanopropylsilyl groups. Less than 20 ppm of metals. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine white or almost white, homogenous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, nitrile, end-capped. *1174500.*

A very finely divided silica gel, chemically modified at the surface by the bonding of cyanopropylsilyl groups. To minimise any interaction with basic components it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the test where it is used.

A fine, white or almost white, homogenous powder, practically insoluble in water and in anhydrous ethanol.

Silica gel for chromatography, octadecanoylaminopropylsilyl. *1115200.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of aminopropylsilyl groups which are acylated with octadecanoyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octadecylsilyl. *1077500.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octadecylsilyl R1. *1110100.*

A very finely divided ultrapure silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups. The particle size, the pore size and the carbon loading are indicated after the name of the reagent in the tests where it is used. Less than 20 ppm of metals.

Silica gel for chromatography, octadecylsilyl R2. *1115300.*

A very finely divided (15 nm pore size) ultrapure silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups (20 per cent carbon load), optimised for the analysis of polycyclic aromatic hydrocarbons. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octadecylsilyl, base-deactivated. *1077600.*

A very finely divided (3 µm-10 µm) silica gel, pretreated before the bonding of octadecylsilyl groups by careful washing and hydrolysing most of the superficial siloxane bridges to minimise the interaction with basic components. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octadecylsilyl, end-capped. *1115400.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups. To minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogenous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octadecylsilyl, end-capped R1. *1115401.*

A very finely divided (10 nm pore size) ultrapure silica gel, chemically modified at the surface by the bonding of octadecylsilyl groups (19 per cent carbon load). To minimise any interaction with basic compounds it is carefully end-capped

to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used. It contains less than 20 ppm of metals.

Silica gel for chromatography, octadecylsilyl, end-capped, base-deactivated. *1108600.*

A very finely divided (3 µm-10 µm) silica gel with a pore size of 10 nm and a carbon loading of 16 per cent, pre-treated before the bonding of octadecylsilyl groups by washing and hydrolysing most of the superficial siloxane bridges. To further minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the test where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octadecylsilyl, end-capped, base-deactivated R1. *1162600.*

A very finely divided (3-10 µm) silica gel pre-treated before the bonding of octadecylsilyl groups by washing and hydrolysing most of the superficial siloxane bridges. To further minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the test where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octadecylsilyl, monolithic. *1154500.*

Monolithic rods of highly porous (greater than 80 per cent) metal-free silica with a bimodal pore structure, modified at the surface by the bonding of octadecylsilyl groups.

Silica gel for chromatography, octadecylsilyl, with embedded polar groups, end-capped. *1177900.*

A very finely divided silica gel (3-10 µm). The particles are based on a mixture of silica chemically modified at the surface by the bonding of octadecylsilyl groups and silica chemically modified with a reagent providing a surface with chains having embedded polar groups. Furthermore, the packing material is end-capped. The particle size is indicated after the name of the reagent in the tests where it is used.

Silica gel for chromatography, octadecylsilyl, with polar incorporated groups, end-capped. *1165100.*

A very finely divided silica gel (3-10 µm). The particles are based on silica, chemically modified with a reagent providing a surface with chains having polar incorporated groups and terminating octadecyl groups. Furthermore, the packing material is end-capped. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder.

Silica gel for chromatography, octylsilyl. *1077700.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of octylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octylsilyl R1. *1077701.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of octylsilyl and methyl groups (double bonded phase). The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octylsilyl R2. *1077702.*

Ultrapure very finely divided (10 nm pore size) silica gel, chemically modified at the surface by the bonding of octylsilyl groups (19 per cent carbon load). Less than 20 ppm of metals.

Silica gel for chromatography, octylsilyl R3. *1155200.*

A very finely divided ultrapure silica gel, chemically modified at the surface by the bonding of octylsilyl groups and sterically protected with branched hydrocarbons at the silanes. The particle size is indicated after the name of the reagent in the tests where it is used.

Silica gel for chromatography, octylsilyl, base-deactivated. *1131600.*

A very finely divided (3 µm-10 µm) silica gel, pretreated before the bonding of octylsilyl groups by careful washing and hydrolysing most of the superficial siloxane bridges to minimise the interaction with basic components. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octylsilyl, end-capped. *1119600.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of octylsilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octylsilyl, end-capped, base-deactivated. *1148800.*

A very finely divided (3 µm-10 µm) silica gel, pre-treated before the bonding of octylsilyl groups by washing and hydrolysing most of the superficial siloxane bridges. To further minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the test where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, octylsilyl, with polar incorporated groups, end-capped. *1152600.*

A very finely divided silica gel (3-10 µm). The particles are based on silica, chemically modified with a reagent providing a surface with chains having polar incorporated groups and terminating octyl groups. Furthermore, the packing material is end-capped. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder.

Silica gel for chromatography, palmitamidopropylsilyl, end-capped. *1161900.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of palmitamidopropyl groups and end-capped with acetamidopropyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for chromatography, phenylhexylsilyl. *1153900.*

A very finely divided silica gel, chemically modified at the surface by the bonding of phenylhexyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Silica gel for chromatography, phenylhexylsilyl, end-capped. *1170600.*

A very finely divided silica gel (3 µm), chemically modified at the surface by the bonding of phenylhexylsilyl groups. To minimise any interaction with basic compounds, it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Silica gel for chromatography, phenylsilyl. *1110200.*

A very finely divided (5 µm-10 µm) silica gel, chemically modified at the surface by the bonding of phenyl groups.

Silica gel for chromatography, phenylsilyl R1. *1075700.*

A very finely divided silica gel (5 µm), chemically modified at the surface by the bonding of phenyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water, in ethanol (96 per cent) and in methylene chloride.

Spheroidal silica: 8 nm.

Specific surface area: 180 m^2/g.

Carbon loading: 5.5 per cent.

Silica gel for chromatography, phenylsilyl, end-capped. *1154900.*

A very finely divided (5-10 µm) silica gel, chemically modified at the surface by the bounding of phenyl groups. To minimise any interaction with basic compounds it is carefully end-capped to cover most of the remaining silanol groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Silica gel for chromatography, propoxybenzene, end-capped. *1174600.*

A very finely divided (3-10 µm) silica gel, chemically modified at the surface by the bonding of propoxybenzene groups. The particle size is indicated after the name of the reagent in the test where it is used.

Silica gel for chromatography, propylsilyl. *1170700.*

A very finely divided silica gel (3-10 µm), chemically modified at the surface by the bonding of propylsilyl groups. The particle size is indicated after the name of the reagent in the test where it is used.

Silica gel for chromatography, strong-anion-exchange. *1077800.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of quaternary ammonium groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

pH limit of use: 2 to 8.

Silica gel for chromatography, strong cation-exchange. *1161400.*

A very finely divided (5-10 µm) silica gel, chemically modified at the surface by the bonding of sulfonic acid groups. The particle size is specified after the name of the reagent in the tests where it is used.

Silica gel for chromatography, trimethylsilyl. *1115500.*

A very finely divided (3 µm-10 µm) silica gel, chemically modified at the surface by the bonding of trimethylsilyl groups. The particle size is indicated after the name of the reagent in the tests where it is used.

Fine, white or almost white, homogeneous powder, practically insoluble in water and in ethanol (96 per cent).

Silica gel for size-exclusion chromatography. *1077900.*

A very finely divided silica gel (10 µm) with a very hydrophilic surface. The average diameter of the pores is about 30 nm. It is compatible with aqueous solutions between pH 2 and 8 and with organic solvents. It is suitable for the separation of proteins with relative molecular masses of 1×10^3 to 3×10^5.

Silica gel G. *1076300.* [112926-00-8].

Contains about 13 per cent of calcium sulfate hemihydrate.

Fine, white or almost white, homogeneous powder with a particle size of about 15 µm.

Calcium sulfate content. Place 0.25 g in a ground-glass stoppered flask, add 3 mL of *dilute hydrochloric acid R* and 100 mL of *water R* and shake vigorously for 30 min. Filter through a sintered-glass filter (*2.1.2*) and wash the residue. Carry out on the combined filtrate and washings the complexometric assay of calcium (*2.5.11*).

1 mL of *0.1 M sodium edetate* is equivalent to 14.51 mg of $CaSO_4,{}^1/_2H_2O$.

pH (*2.2.3*). Shake 1 g for 5 min with 10 mL of *carbon dioxide-free water R*. The pH of the suspension is about 7.

Silica gel GF_{254}. *1076400.* [112926-00-8].

Contains about 13 per cent of calcium sulfate hemihydrate and about 1.5 per cent of a fluorescent indicator having an optimal intensity at 254 nm.

Fine, white or almost white, homogeneous powder with a particle size of about 15 µm.

Calcium sulfate content. Determine by the method prescribed for *silica gel G R*.

pH (2.2.3). Complies with the test prescribed for *silica gel G R*.

Fluorescence. Thin-layer chromatography (*2.2.27*) using *silica gel GF_{254} R* as the coating substance. Apply separately to the plate at ten points increasing volumes from 1 µL to 10 µL of a 1 g/L solution of *benzoic acid R* in a mixture of 10 volumes of *anhydrous formic acid R* and 90 volumes of *2-propanol R*. Develop over a path of 10 cm with the same mixture of solvents. After evaporating the solvents examine the chromatogram in ultraviolet light at 254 nm. The benzoic acid appears as dark spots on a fluorescent background in the upper third of the chromatogram for quantities of 2 µg and greater.

Silica gel H. *1076500.* [112926-00-8].

Fine, white or almost white, homogeneous powder with a particle size of about 15 µm.

pH (2.2.3). Complies with the test prescribed for *silica gel G R*.

Silica gel H, silanised. *1076600.*

Preparation of a thin layer. See *silanised silica gel HF_{254} R*.

A fine, white or almost white homogeneous powder which, after being shaken with water, floats on the surface because of its water-repellent properties.

Chromatographic separation. Complies with the test prescribed for *silanised silica gel HF_{254} R*.

Silica gel HF_{254}. *1076700.*

Contains about 1.5 per cent of a fluorescent indicator having an optimal intensity at 254 nm.

Fine, white or almost white, homogeneous powder with a particle size of about 15 µm.

pH. Complies with the test prescribed for *silica gel G R*.

Fluorescence. Complies with the test prescribed for *silica gel GF_{254} R*.

Silica gel HF_{254}, silanised. *1076800.*

Contains about 1.5 per cent of a fluorescent indicator having an optimal intensity at 254 nm.

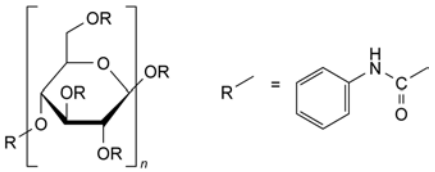
Fine, white or almost white, homogeneous powder which, after shaking with water, floats on the surface because of its water-repellent properties.

Preparation of a thin layer. Vigorously shake 30 g for 2 min with 60 mL of a mixture of 1 volume of *methanol R* and 2 volumes of *water R*. Coat carefully cleaned plates with a layer 0.25 mm thick using a spreading device. Allow the coated plates to dry in air and then heat in an oven at 100 °C to 105 °C for 30 min.

Chromatographic separation. Introduce 0.1 g each of *methyl laurate R, methyl myristate R, methyl palmitate R* and *methyl stearate R* into a 250 mL conical flask. Add 40 mL of *alcoholic potassium hydroxide solution R* and heat under a reflux condenser on a water-bath for 1 h. Allow to cool, transfer the solution to a separating funnel by means of 100 mL of *water R*, acidify (pH 2 to 3) with *dilute hydrochloric acid R* and shake with three quantities, each of 10 mL of *chloroform R*. Dry the combined chloroform extracts over *anhydrous sodium sulfate R*, filter and evaporate to dryness on a water-bath. Dissolve the residue in 50 mL of *chloroform R*. Examine by thin-layer chromatography (*2.2.27*), using silanised silica gel HF_{254} as the coating substance. Apply to the plate at each of three separate points 10 µL of the chloroformic solution. Develop over a path of 14 cm with a mixture of 10 volumes of *glacial acetic acid R*, 25 volumes of *water R* and 65 volumes of *dioxan R*. Dry the plate at 120 °C for 30 min. Allow to cool, spray with a 35 g/L solution of *phosphomolybdic acid R* in *2-propanol R* and heat at 150 °C until the spots become visible. Treat the plate with ammonia vapour until the background is white. The chromatograms show four clearly separated, well-defined spots.

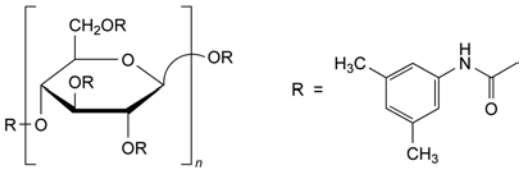
Silica gel OC for chiral separations. *1146800.*

A very finely divided silica gel for chromatography (5 µm) coated with the following derivative:



Silica gel OD for chiral separations. *1110300.*

A very finely divided silica gel for chromatography (5 µm) coated with the following derivative:



Silicotungstic acid. $H_4SiW_{12}O_{40},xH_2O$. *1078000.* [11130-20-4].

White or yellowish-white crystals, deliquescent, very soluble in water and in ethanol (96 per cent).

Storage: in an airtight container.

Silicristin. $C_{25}H_{22}O_{10}$. (M_r 482.4). *1151500.* [33889-69-9]. (2*R*,3*R*)-3,5,7-Trihydroxy-2-[(2*R*,3*S*)-7-hydroxy-2-(4-hydroxy-3-methoxyphenyl)-3-hydroxymethyl-2,3-dihydro-1-benzofuran-5-yl]chroman-4-one.

White or yellowish powder, practically insoluble in water, soluble in acetone and in methanol.

Silidianin. $C_{25}H_{22}O_{10}$. (M_r 482.4). *1151600.* [29782-68-1]. (3*R*,3a*R*,6*R*,7a*R*,8*R*)-7a-Hydroxy-8-(4-hydroxy-3-methoxyphenyl)-4-[(2*R*, 3*R*)-3,5,7-trihydroxy-4-oxochroman-2-yl]-2,3,3a,7a-tetrahydro-3,6-methano-1-benzofuran-7(6a*H*)-one.

White or yellowish powder, practically insoluble in water, soluble in acetone and in methanol.

Silver diethyldithiocarbamate. $C_5H_{10}AgNS_2$. (M_r 256.1). *1110400.* [1470-61-7].

Pale-yellow or greyish-yellow powder, practically insoluble in water, soluble in pyridine.

It may be prepared as follows. Dissolve 1.7 g of *silver nitrate R* in 100 mL of *water R*. Separately dissolve 2.3 g of *sodium diethyldithiocarbamate R* in 100 mL of *water R*. Cool both solutions to 10 °C, then mix and while stirring collect the yellow precipitate on a sintered-glass filter (*2.1.2*) and wash with 200 mL of cold *water R*. Dry the precipitate *in vacuo* for 2-3 h.

Silver diethyldithiocarbamate may be used provided it has not changed in colour or developed a strong odour.

Silver manganese paper. *1078200.*

Immerse strips of slow filter paper into a solution containing 8.5 g/L of *manganese sulfate R* and 8.5 g/L of *silver nitrate R*. Maintain for a few minutes and allow to dry over *diphosphorus pentoxide R* protected from acid and alkaline vapours.

Silver nitrate. *1078300.* [7761-88-8].

See *Silver nitrate (0009)*.

Silver nitrate reagent. *1078305.*

To a mixture of 3 mL of *concentrated ammonia R* and 40 mL of *1 M sodium hydroxide*, add 8 mL of a 200 g/L solution of *silver nitrate R*, dropwise, with stirring. Dilute to 200 mL with *water R*.

Silver nitrate solution R1. *1078301.*

A 42.5 g/L solution.

Storage: protected from light.

Silver nitrate solution R2. *1078302.*

A 17 g/L solution.

Storage: protected from light.

Silver nitrate solution, ammoniacal. *1078303.*

Dissolve 2.5 g of *silver nitrate R* in 80 mL of *water R* and add *dilute ammonia R1* dropwise until the precipitate has dissolved. Dilute to 100 mL with *water R*. Prepare immediately before use.

Silver nitrate solution in pyridine. *1078304.*

An 85 g/L solution in *pyridine R*.

Storage: protected from light.

Silver oxide. Ag_2O. (M_r 231.7). *1078400.* [20667-12-3]. Disilver oxide.

Brownish-black powder, practically insoluble in water and in ethanol (96 per cent), freely soluble in dilute nitric acid and in ammonia.

Storage: protected from light.

Sinensetin. $C_{20}H_{20}O_7$. (M_r 372.4). *1110500.* [2306-27-6]. 3′,4′,5,6,7-Pentamethoxyflavone.

White or almost white, crystalline powder, practically insoluble in water, soluble in ethanol (96 per cent).

mp: about 177 °C.

Absorbance (*2.2.25*). A solution in *methanol R* shows 3 absorption maxima, at 243 nm, 268 nm and 330 nm.

Assay. Liquid chromatography (*2.2.29*) as prescribed in the monograph *Java tea (1229)*.

Content: minimum 95 per cent, calculated by the normalisation procedure.

Sitostanol. $C_{29}H_{52}O$. (M_r 416.7). *1140100.* [19466-47-8]. Dihydro-β-sitosterol.

Content: minimum 95.0 per cent.

β-Sitosterol. $C_{29}H_{50}O$. (M_r 414.7). *1140200.* [83-46-5]. Stigmast-5-en-3β-ol. 22,23-Dihydrostigmasterol.

White or almost white powder, practically insoluble in water, sparingly soluble in tetrahydrofuran.

Content: minimum 75.0 per cent *m/m* (dried substance).

Assay. Gas chromatography (*2.2.28*), as prescribed in the monograph *Phytosterol (1911)*.

Test solution. Dissolve 0.100 g of the substance to be examined in *tetrahydrofuran R* and dilute to 10.0 mL with the same solvent. Introduce 100 µL of this solution into a suitable 3 mL flask and evaporate to dryness under *nitrogen R*. To the residue add 100 µL of a freshly prepared mixture of 50 µL of *1-methylimidazole R* and 1.0 mL of *heptafluoro-N-methyl-N-(trimethylsilyl)butanamide R*. Close the flask tightly and heat at 100 °C for 15 min. Allow to cool.

Injection: 1 µL of the test solution.

Sodium. Na. (A_r 22.99). *1078500.* [7440-23-5].

A metal whose freshly cut surface is bright silver-grey. It rapidly tarnishes in contact with air and is oxidised completely to sodium hydroxide and converted to sodium carbonate. It reacts violently with water, yielding hydrogen and a solution of sodium hydroxide; soluble in anhydrous methanol, yielding hydrogen and a solution of sodium methoxide; practically insoluble in light petroleum.

Storage: under light petroleum or liquid paraffin.

Sodium acetate. *1078600.* [6131-90-4].

See *Sodium acetate trihydrate (0411)*.

Sodium acetate, anhydrous. $C_2H_3NaO_2$. (M_r 82.0). *1078700.* [127-09-3].

Colourless crystals or granules, very soluble in water, sparingly soluble in ethanol (96 per cent).

Loss on drying (*2.2.32*). Not more than 2.0 per cent, determined by drying in an oven at 105 °C.

Sodium arsenite. $NaAsO_2$. (M_r 129.9). *1165900.* [7784-46-5]. Sodium metaarsenite.

Sodium arsenite solution. *1165901.*

Dissolve 5.0 g of *sodium arsenite R* in 30 mL of *1 M sodium hydroxide*. Cool to 0 °C and add, while stirring, 65 mL of *dilute hydrochloric acid R*.

Sodium ascorbate solution. *1078800.* [134-03-2].

Dissolve 3.5 g of *ascorbic acid R* in 20 mL of *1 M sodium hydroxide*. Prepare immediately before use.

Sodium azide. NaN_3. (M_r 65.0). *1078900.* [26628-22-8].

White or almost white, crystalline powder or crystals, freely soluble in water, slightly soluble in ethanol (96 per cent).

Sodium bicarbonate. *1081300.* [144-55-8].

See *sodium hydrogen carbonate R*.

Sodium bismuthate. $NaBiO_3$. (M_r 280.0). *1079000.* [12232-99-4].

Content: minimum 85.0 per cent.

Yellow or yellowish-brown powder, slowly decomposing when moist or at a high temperature, practically insoluble in cold water.

Assay. Suspend 0.200 g in 10 mL of a 200 g/L solution of *potassium iodide R* and add 20 mL of *dilute sulfuric acid R*. Using 1 mL of *starch solution R* as indicator, titrate with *0.1 M sodium thiosulfate* until an orange colour is obtained.

1 mL of *0.1 M sodium thiosulfate* is equivalent to 14.00 mg of $NaBiO_3$.

Sodium bromide. *1154300.* [7647-15-6].

See *Sodium bromide (0190)*.

Sodium butanesulfonate. $C_4H_9NaO_3S$. (M_r 160.2). *1115600.* [2386-54-1].

White or almost white, crystalline powder, soluble in water.

mp: greater than 300 °C.

Sodium calcium edetate. *1174000.* [62-33-9].

See *sodium calcium edetate (0231)*.

Sodium carbonate. *1079200.* [6132-02-1].

See *Sodium carbonate decahydrate (0191)*.

Sodium carbonate, anhydrous. Na_2CO_3. (M_r 106.0). *1079300.* [497-19-8]. Disodium carbonate.

White or almost white powder, hygroscopic, freely soluble in water.

When heated to about 300 °C it loses not more than 1 per cent of its mass.

Storage: in an airtight container.

Sodium carbonate solution. *1079301.*

A 106 g/L solution of *anhydrous sodium carbonate R*.

Sodium carbonate solution R1. *1079302.*

A 20 g/L solution of *anhydrous sodium carbonate R* in *0.1 M sodium hydroxide*.

Sodium carbonate solution R2. *1079303.*

A 40 g/L solution of *anhydrous sodium carbonate R* in *0.2 M sodium hydroxide*.

Sodium carbonate monohydrate. *1131700.* [5968-11-6].

See *Sodium carbonate monohydrate (0192)*.

Sodium cetostearyl sulfate. *1079400.*

See *Sodium cetostearyl sulfate (0847)*.

Sodium chloride. *1079500.* [7647-14-5].

See *Sodium chloride (0193)*.

Sodium chloride solution. *1079502.*

A 20 per cent *m/m* solution.

Sodium chloride solution, saturated. *1079503.*

Mix 1 part of *sodium chloride R* with 2 parts of *water R*, shake from time to time and allow to stand. Before use, decant the solution from any undissolved substance and filter, if necessary.

Sodium citrate. *1079600.* [6132-04-3].

See *Sodium citrate (0412)*.

Sodium cobaltinitrite. $Na_3[Co(NO_2)_6]$. (M_r 403.9). *1079700.* [13600-98-1]. Trisodium hexanitrocobaltate(III).

Orange-yellow powder, freely soluble in water, slightly soluble in ethanol (96 per cent).

Sodium cobaltinitrite solution. *1079701.*

A 100 g/L solution. Prepare immediately before use.

Sodium decanesulfonate. $C_{10}H_{21}NaO_3S$. (M_r 244.3). *1079800.* [13419-61-9].

Crystalline powder or flakes, white or almost white, freely soluble in water, soluble in methanol.

Sodium decyl sulfate. $C_{10}H_{21}NaO_4S$. (M_r 260.3). *1138600.* [142-87-0].

Content: minimum 95.0 per cent.

White or almost white powder, freely soluble in water.

Sodium deoxycholate. $C_{24}H_{39}NaO_4$. (M_r 414.6). *1131800.* [302-95-4]. Sodium 3α,12α-dihydroxy-5β-cholan-24-oate.

Sodium deoxyribonucleate. (About 85 per cent has a relative molecular mass of 2×10^7 or greater). *1079900.* [73049-39-5].

White or almost white, fibrous preparation obtained from calf thymus.

Test for suitability. Dissolve 10 mg in *imidazole buffer solution pH 6.5 R* and dilute to 10.0 mL with the same buffer solution (solution A). Dilute 2.0 mL of solution A to 50.0 mL with *imidazole buffer solution pH 6.5 R*. The absorbance (*2.2.25*) of the solution, measured at 260 nm, is 0.4 to 0.8.

To 0.5 mL of solution A add 0.5 mL of *imidazole buffer solution pH 6.5 R* and 3 mL of perchloric acid (25 g/L $HClO_4$). A precipitate is formed. Centrifuge. The absorbance of the supernatant liquid, measured at 260 nm using a mixture of 1 mL of *imidazole buffer solution pH 6.5 R* and 3 mL of perchloric acid (25 g/L $HClO_4$) as compensation liquid, is not greater than 0.3.

In each of two tubes, place 0.5 mL of solution A and 0.5 mL of a solution of a reference preparation of streptodornase containing 10 IU/mL in *imidazole buffer solution pH 6.5 R*. To one tube add immediately 3 mL of perchloric acid (25 g/L $HClO_4$). A precipitate is formed. Centrifuge and collect the supernatant liquid A. Heat the other tube at 37 °C for 15 min and add 3 mL of perchloric acid (25 g/L $HClO_4$). Centrifuge and collect the supernatant liquid B. The absorbance of supernatant liquid B, measured at 260 nm with reference to supernatant liquid A is not less than 0.15.

Sodium diethyldithiocarbamate. $C_5H_{10}NNaS_2,3H_2O$. (M_r 225.3). *1080000.* [20624-25-3].

White or almost white or colourless crystals, freely soluble in water, soluble in ethanol (96 per cent). The aqueous solution is colourless.

Sodium dihydrogen phosphate. *1080100.* [13472-35-0].

See *Sodium dihydrogen phosphate dihydrate (0194).*

Sodium dihydrogen phosphate, anhydrous. NaH_2PO_4. (M_r 120.0). *1080200.* [7558-80-7].

White or almost white powder, hygroscopic.

Storage: in an airtight container.

Sodium dihydrogen phosphate monohydrate. NaH_2PO4,H_2O. (M_r 138.0). *1080300.* [10049-21-5].

White or almost white, slightly deliquescent crystals or granules, freely soluble in water, practically insoluble in ethanol (96 per cent).

Storage: in an airtight container.

Sodium dioctyl sulfosuccinate. $C_{20}H_{37}NaO_7S$. (M_r 444.6). *1170800.* [577-11-7]. Sodium 1,4-bis[(2-ethylhexyl)oxy]-1,4-dioxobutane-2-sulfonate. 1,4-Bis(2-ethylhexyl) sulfobutanedioate sodium salt.

White or almost white, waxy solid.

Sodium dithionite. $Na_2S_2O_4$. (M_r 174.1). *1080400.* [7775-14-6].

White or greyish-white, crystalline powder, oxidises in air, very soluble in water, slightly soluble in ethanol (96 per cent).

Storage: in an airtight container.

Sodium dodecyl sulfate. *1080500.* [151-21-3].

See *Sodium laurilsulfate (0098).*

Content: minimum 99.0 per cent.

Sodium edetate. *1080600.* [6381-92-6].

See *Disodium edetate (0232).*

Sodium fluoresceinate. $C_{20}H_{10}Na_2O_5$. (M_r 376.3). *1080700.* [518-47-8].

Schultz No. 880.

Colour Index No. 45350.
Fluorescein sodium. Disodium 2-(3-oxo-6-oxido-3H-xanthen-9-yl)benzoate.

Orange-red powder, freely soluble in water. Aqueous solutions display an intense yellowish-green fluorescence.

Sodium fluoride. *1080800.* [7681-49-4].

See *Sodium fluoride (0514).*

Sodium formate. $CHNaO_2$. (M_r 68.0). *1122200.* [141-53-7]. Sodium methanoate.

White or almost white, crystalline powder or deliquescent granules, soluble in water and in glycerol, slightly soluble in ethanol (96 per cent).

mp: about 253 °C.

Sodium glucuronate. $C_6H_9NaO_7,H_2O$. (M_r 234.1). *1080900.* Sodium D-glucuronate monohydrate.

$[\alpha]_D^{20}$: about + 21.5, determined on a 20 g/L solution.

Sodium glycocholate. $C_{26}H_{42}NNaO_6,2H_2O$. (M_r 523.6). *1155500.* [207300-80-9]. Sodium [(3,7,12-trihydroxy-5-cholan-24-oyl)amino]acetate dihydrate. *N*-[(3,5,7,12)-3,7,12-Trihydroxy-24-oxocholan-24-yl]glycine monosodium salt dihydrate.

Content: minimum 97 per cent of $C_{26}H_{42}NNaO_6,2H_2O$.

Sodium heptanesulfonate. $C_7H_{15}NaO_3S$. (M_r 202.3). *1081000.* [22767-50-6].

White or almost white, crystalline mass, freely soluble in water, soluble in methanol.

Sodium heptanesulfonate monohydrate. $C_7H_{15}NaO_3S,H_2O$. (M_r 220.3). *1081100.*

Content: minimum 96 per cent (anhydrous substance).

White or almost white, crystalline powder, soluble in water, very slightly soluble in anhydrous ethanol.

Water (*2.5.12*): maximum 8 per cent, determined on 0.300 g.

Assay. Dissolve 0.150 g in 50 mL of *anhydrous acetic acid R*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

1 mL of *0.1 M perchloric acid* is equivalent to 20.22 mg of $C_7H_{15}NaO_3S$.

Sodium hexanesulfonate. $C_6H_{13}NaO_3S$. (M_r 188.2). *1081200.* [2832-45-3].

White or almost white powder, freely soluble in water.

Sodium hexanesulfonate monohydrate. $C_6H_{13}NaO_3S,H_2O$. (M_r 206.2). *1161500.* [207300-91-2].

White or almost white powder, soluble in water.

Sodium hydrogen carbonate. *1081300.* [144-55-8].

See *Sodium hydrogen carbonate (0195).*

Sodium hydrogen carbonate solution. *1081301.*

A 42 g/L solution.

Sodium hydrogen sulfate. $NaHSO_4$. (M_r 120.1). *1131900.* [7681-38-1]. Sodium bisulfate.

Freely soluble in water, very soluble in boiling water. It decomposes in ethanol (96 per cent) into sodium sulfate and free sulfuric acid.

mp: about 315 °C.

Sodium hydrogensulfite. $NaHO_3S$. (M_r 104.1). *1115700.* [7631-90-5].

White or almost white, crystalline powder, freely soluble in water, sparingly soluble in ethanol (96 per cent).

On exposure to air, some sulfur dioxide is lost and the substance is gradually oxidated to sulfate.

Sodium hydroxide. *1081400.* [1310-73-2].

See *Sodium hydroxide (0677).*

2 M Sodium hydroxide. *3009800.*

Dissolve 84 g of *sodium hydroxide R* in *carbon dioxide-free water R* and dilute to 1000.0 mL with the same solvent.

Sodium hydroxide solution. *1081401.*

Dissolve 20.0 g of *sodium hydroxide R* in *water R* and dilute to 100.0 mL with the same solvent. Verify the concentration by titration with *1 M hydrochloric acid*, using *methyl orange solution R* as indicator, and adjust if necessary to 200 g/L.

Sodium hydroxide solution, carbonate-free. *1081406.*

Dissolve *sodium hydroxide R* in *carbon dioxide-free water R* to give a concentration of 500 g/L and allow to stand. Decant the clear supernatant liquid, taking precautions to avoid the introduction of carbon dioxide.

Sodium hydroxide solution, dilute. *1081402.*

Dissolve 8.5 g of *sodium hydroxide R* in *water R* and dilute to 100 mL with the same solvent.

Sodium hydroxide solution, methanolic. *1081403.*

Dissolve 40 mg of *sodium hydroxide R* in 50 mL of *water R*. Cool and add 50 mL of *methanol R*.

Sodium hydroxide solution, methanolic R1. *1081405.*

Dissolve 200 mg of *sodium hydroxide R* in 50 mL of *water R*. Cool and add 50 mL of *methanol R*.

Sodium hydroxide solution, strong. *1081404.*

Dissolve 42 g of *sodium hydroxide R* in *water R* and dilute to 100 mL with the same solvent.

Sodium 2-hydroxybutyrate. $C_4H_7NaO_3$. (M_r 126.1). *1158800.* [19054-57-0]. Sodium (2*RS*)-2-hydroxybutanoate.

Sodium hypobromite solution. *1081500.*

In a bath of iced water mix 20 mL of *strong sodium hydroxide solution R* and 500 mL of *water R*, add 5 mL of *bromine solution R* and stir gently until solution is complete. Prepare immediately before use.

Sodium hypochlorite solution, strong. *1081600.*

Content: 25 g/L to 30 g/L of active chlorine.

Yellowish liquid with an alkaline reaction.

Assay. Introduce into a flask, successively, 50 mL of *water R*, 1 g of *potassium iodide R* and 12.5 mL of *dilute acetic acid R*. Dilute 10.0 mL of the substance to be examined to 100.0 mL with *water R*. Introduce 10.0 mL of this solution into the flask and titrate with *0.1 M sodium thiosulfate*, using 1 mL of *starch solution R* as indicator.

1 mL of *0.1 M sodium thiosulfate* is equivalent to 3.546 mg of active chlorine.

Storage: protected from light.

Sodium hypophosphite. NaH_2PO_2,H_2O. (M_r 106.0). *1081700.* [10039-56-2]. Sodium phosphinate monohydrate.

White or almost white, crystalline powder or colourless crystals, hygroscopic, freely soluble in water, soluble in ethanol (96 per cent).

Storage: in an airtight container.

Sodium iodide. *1081800.* [7681-82-5].

See *Sodium iodide (0196)*.

Sodium laurilsulfate. *1081900.* [151-21-3].

See *Sodium laurilsulfate (0098)*.

Sodium lauryl sulfate. *1081900.* [151-21-3].

See *Sodium laurilsulfate R*.

Sodium laurylsulfonate for chromatography. $C_{12}H_{25}NaO_3S$. (M_r 272.4). *1132000.* [2386-53-0].

White or almost white powder or crystals, freely soluble in water.

Absorbance $A_{1\text{ cm}}^{5\%}$ (*2.2.25*), determined in *water R*: about 0.05 at 210 nm; about 0.03 at 220 nm; about 0.02 at 230 nm; about 0.02 at 500 nm.

Sodium metabisulfite. *1082000.* [7681-57-4].

See *Sodium metabisulfite (0849)*.

Sodium methanesulfonate. CH_3SO_3Na. (M_r 118.1). *1082100.* [2386-57-4].

White or almost white, crystalline powder, hygroscopic.

Storage: in an airtight container.

Sodium molybdate. $Na_2MoO_4,2H_2O$. (M_r 242.0). *1082200.* [10102-40-6]. Disodium molybdate dihydrate.

White or almost white, crystalline powder or colourless crystals, freely soluble in water.

Sodium naphthoquinonesulfonate. $C_{10}H_5NaO_5S$. (M_r 260.2). *1082300.* [521-24-4]. Sodium 1,2-naphthoquinone-4-sulfonate.

Yellow or orange-yellow, crystalline powder, freely soluble in water, practically insoluble in ethanol (96 per cent).

Sodium nitrate. $NaNO_3$. (M_r 85.0). *1082400.* [7631-99-4].

White or almost white powder or granules or colourless, transparent crystals, deliquescent in moist air, freely soluble in water, slightly soluble in ethanol (96 per cent).

Storage: in an airtight container.

Sodium nitrite. $NaNO_2$. (M_r 69.0). *1082500.* [7632-00-0].

Content: minimum 97.0 per cent.

White or almost white, granular powder or a slightly yellow, crystalline powder, freely soluble in water.

Assay. Dissolve 0.100 g in 50 mL of *water R*. Add 50.0 mL of *0.02 M potassium permanganate* and 15 mL of *dilute sulfuric acid R*. Add 3 g of *potassium iodide R*. Titrate with *0.1 M sodium thiosulfate*, using 1.0 mL of *starch solution R* added towards the end of the titration as indicator.

1 mL of *0.02 M potassium permanganate* is equivalent to 3.450 mg of $NaNO_2$.

Sodium nitrite solution. *1082501.*

A 100 g/L solution. Prepare immediately before use.

Sodium nitroprusside. $Na_2[Fe(CN)_5(NO)],2H_2O$. (M_r 298.0). *1082600.* [13755-38-9]. Sodium pentacyano-nitrosylferrate(III) dihydrate.

Reddish-brown powder or crystals, freely soluble in water, slightly soluble in ethanol (96 per cent).

Sodium octanesulfonate. $C_8H_{17}NaO_3S$. (M_r 216.3). *1082700.* [5324-84-5].

Content: minimum 98.0 per cent.

White or almost white, crystalline powder or flakes, freely soluble in water, soluble in methanol.

Absorbance (*2.2.25*): maximum 0.10, determined at 200 nm and maximum 0.01, determined at 250 nm using a 54 g/L solution.

Sodium octanesulfonate monohydrate. $C_8H_{17}NaO_3S,H_2O$. (M_r 234.3). *1176700.* [207596-29-0].

White or almost white powder.

Sodium octyl sulfate. $C_8H_{17}NaO_4S$. (M_r 232.3). *1082800.* [142-31-4].

White or almost white, crystalline powder or flakes, freely soluble in water, soluble in methanol.

Sodium oxalate. $C_2Na_2O_4$. (M_r 134.0). *1082900.* [62-76-0].

White or almost white, crystalline powder, soluble in water, practically insoluble in ethanol (96 per cent).

Sodium pentanesulfonate. $C_5H_{11}NaO_3S$. (M_r 174.2). *1083000.* [22767-49-3].

White or almost white, crystalline solid, soluble in water.

Sodium pentanesulfonate monohydrate. $C_5H_{11}NaO_3S,H_2O$. (M_r 192.2). *1132100.* [22767-49-3].

White or almost white crystalline solid, soluble in water.

Sodium pentanesulfonate monohydrate R1. $C_5H_{11}NaO_3S,H_2O$. (M_r 192.2). *1172500.* [22767-49-3].

Content: minimum 99 per cent of $C_5H_{11}NaO_3S,H_2O$.

Sodium perchlorate. $NaClO_4,H_2O$. (M_r 140.5). *1083100.* [7791-07-3].

Content: minimum 99.0 per cent of $NaClO_4,H_2O$.

White or almost white, deliquescent crystals, very soluble in water.

Storage: in a well-closed container.

Sodium periodate. $NaIO_4$. (M_r 213.9). *1083200.* [7790-28-5]. Sodium metaperiodate.

Content: minimum 99.0 per cent.

White or almost white, crystalline powder or crystals, soluble in water and in mineral acids.

Sodium periodate solution. *1083201.*

Dissolve 1.07 g of *sodium periodate R* in *water R*, add 5 mL of *dilute sulfuric acid R* and dilute to 100.0 mL with *water R*. Use a freshly prepared solution.

Sodium phosphite pentahydrate. $Na_2HPO_3,5H_2O$. (M_r 216.0). *1132200.* [13517-23-2].

White or almost white, crystalline powder, hygroscopic, freely soluble in water.

Storage: in an airtight container.

Sodium picrate solution, alkaline. *1083300.*

Mix 20 mL of *picric acid solution R* and 10 mL of a 50 g/L solution of *sodium hydroxide R* and dilute to 100 mL with *water R*.

Storage: use within 2 days.

Sodium potassium tartrate. $C_4H_4KNaO_6,4H_2O$. (M_r 282.2). *1083500.* [6381-59-5].

Colourless, prismatic crystals, very soluble in water.

Sodium pyrophosphate. $Na_4P_2O_7,10H_2O$. (M_r 446.1). *1083600.* [13472-36-1]. Tetrasodium diphosphate decahydrate.

Colourless, slightly efflorescent crystals, freely soluble in water.

Sodium rhodizonate. $C_6Na_2O_6$. (M_r 214.0). *1122300.* [523-21-7]. [(3,4,5,6-Tetraoxocyclohex-1-en-1,2-ylene)dioxy]disodium.

Violet crystals, soluble in water with an orange-yellow colour.

Solutions are unstable and must be prepared on the day of use.

Sodium salicylate. *1083700.* [54-21-7].

See *Sodium salicylate (0413).*

Sodium sulfate, anhydrous. *1083800.* [7757-82-6].

Ignite at 600 °C to 700 °C anhydrous sodium sulfate complying with the requirements prescribed in the monograph on *Anhydrous sodium sulfate (0099).*

Loss on drying (*2.2.32*): maximum 0.5 per cent, determined by drying in an oven at 130 °C.

Sodium sulfate decahydrate. $Na_2SO_4,10H_2O$. (M_r 322.2). *1132300.* [7727-73-3].

See *Sodium sulfate decahydrate (0100).*

Sodium sulfide. $Na_2S,9H_2O$. (M_r 240.2). *1083900.* [1313-84-4]. Disodium sulfide nonahydrate.

Colourless, rapidly yellowing crystals, deliquescent, very soluble in water.

Storage: in an airtight container.

Sodium sulfide solution. *1083901.*

Dissolve 12 g of *sodium sulfide R* with heating in 45 mL of a mixture of 10 volumes of *water R* and 29 volumes of *glycerol (85 per cent) R*, allow to cool and dilute to 100 mL with the same mixture of solvents.

The solution should be colourless.

Sodium sulfide solution R1. *1083902.*

Prepare by one of the following methods.

— Dissolve 5 g of *sodium sulfide R* in a mixture of 10 mL of *water R* and 30 mL of *glycerol R*.

— Dissolve 5 g of *sodium hydroxide R* in a mixture of 30 mL of *water R* and 90 mL of *glycerol R*. Divide the solution into 2 equal portions. Saturate 1 portion with *hydrogen sulfide R*, with cooling. Mix the 2 portions.

Storage: in a well-filled container, protected from light; use within 3 months.

Sodium sulfite. *1084000.* [10102-15-5].

See *Sodium sulfite heptahydrate (0776).*

Sodium sulfite, anhydrous. *1084100.* [7757-83-7].

See *Anhydrous sodium sulfite (0775).*

Sodium tartrate. $C_4H_4Na_2O_6,2H_2O$. (M_r 230.1). *1084200.* [6106-24-7]. Disodium (2*R*,3*R*)-2,3-dihydroxybutanedioate dihydrate.

White or almost white crystals or granules, very soluble in water, practically insoluble in ethanol (96 per cent).

Sodium taurodeoxycholate. $C_{26}H_{44}NNaO_6S,H_2O$. (M_r 539.7). *1155600.* [110026-03-4]. Sodium 2-[(3,12-dihydroxy-5-cholan-24-oyl)amino]ethanesulfonate monohydrate. 2-[[(3,5,12)-3,12-Dihydroxy-24-oxocholan-24-yl]amino]ethanesulfonic acid monosodium salt monohydrate.

Content: minimum 94 per cent of $C_{26}H_{44}NNaO_6S,H_2O$.

Sodium tetradeuteriodimethylsilapentanoate. $C_6H_9{}^2H_4NaO_2Si$. (M_r 172.3). *1084300.* TSP. Sodium (2,2,3,3-tetradeuterio)-4,4-dimethyl-4-silapentanoate.

Degree of deuteration: minimum 99 per cent.

White or almost white, crystalline powder, freely soluble in water, in anhydrous ethanol and in methanol.

mp: about 300 °C.

Water and deuterium oxide: maximum 0.5 per cent.

Sodium tetrahydroborate. $NaBH_4$. (M_r 37.8). *1146900.* [16940-66-2]. Sodium borohydride.

Colourless, hygroscopic crystals, freely soluble in water, soluble in anhydrous ethanol, decomposing at higher temperature or in the presence of acids or certain metal salts forming borax and hydrogen.

Storage: in an airtight container.

Sodium tetrahydroborate reducing solution. *1146901.*

Introduce about 100 mL of *water R* into a 500 mL volumetric flask containing a stirring bar. Add 5.0 g of *sodium hydroxide R* in pellets and 2.5 g of *sodium tetrahydroborate R*. Stir until complete dissolution, dilute to 500.0 mL with *water R* and mix. Prepare immediately before use.

Sodium tetraphenylborate. $NaB(C_6H_5)_4$. (M_r 342.2). *1084400.* [143-66-8].

White or slightly yellowish, bulky powder, freely soluble in water and in acetone.

Sodium tetraphenylborate solution. *1084401.*

Filter before use if necessary.

A 10 g/L solution.

Storage: use within 1 week.

Sodium thioglycollate. $C_2H_3NaO_2S$. (M_r 114.1). *1084500.* [367-51-1]. Sodium mercaptoacetate.

White or almost white, granular powder or crystals, hygroscopic, freely soluble in water and in methanol, slightly soluble in ethanol (96 per cent).

Storage: in an airtight container.

Sodium thiosulfate. *1084600.* [10102-17-7].

See *Sodium thiosulfate (0414).*

Sodium tungstate. $Na_2WO_4,2H_2O$. (M_r 329.9). *1084700.* [10213-10-2]. Disodium tungstate dihydrate.

White or almost white, crystalline powder or colourless crystals, freely soluble in water forming a clear solution, practically insoluble in ethanol (96 per cent).

Sorbitol. *1084800.* [50-70-4].

See *Sorbitol (0435).*

Squalane. $C_{30}H_{62}$. (M_r 422.8). *1084900.* [111-01-3]. 2,6,10,15,19,23-Hexamethyltetracosane.

Colourless, oily liquid, freely soluble in fatty oils, slightly soluble in acetone, in ethanol (96 per cent), in glacial acetic acid and in methanol.

d_{20}^{20}: 0.811 to 0.813.

n_D^{20}: 1.451 to 1.453.

Stannous chloride. $SnCl_2,2H_2O$. (M_r 225.6). *1085000.* [10025-69-1]. Tin dichloride dihydrate.

Content: minimum 97.0 per cent of $SnCl_2,2H_2O$.

Colourless crystals, very soluble in water, freely soluble in ethanol (96 per cent), in glacial acetic acid and in dilute and concentrated hydrochloric acid.

Assay. Dissolve 0.500 g in 15 mL of *hydrochloric acid R* in a ground-glass-stoppered flask. Add 10 mL of *water R* and 5 mL of *chloroform R*. Titrate rapidly with *0.05 M potassium iodate* until the chloroform layer is colourless.

1 mL of *0.05 M potassium iodate* is equivalent to 22.56 mg of $SnCl_2,2H_2O$.

Stannous chloride solution. *1085001.*

Heat 20 g of *tin R* with 85 mL of *hydrochloric acid R* until no more hydrogen is released. Allow to cool.

Storage: over an excess of *tin R*, protected from air.

Stannous chloride solution R1. *1085002.*

Immediately before use, dilute 1 volume of *stannous chloride solution R* with 10 volumes of *dilute hydrochloric acid R*.

Stannous chloride solution R2. *1085003.*

To 8 g of *stannous chloride R* add 100 mL of a 20 per cent *V/V* solution of *hydrochloric acid R*. Shake until dissolved, heating, if necessary, on a water-bath at 50 °C. Pass a current of *nitrogen R* for 15 min. Prepare immediately before use.

Stanolone. $C_{19}H_{30}O_2$. (M_r 290.4). *1154400.* [521-18-6]. 17β-Hydroxy-5α-androstan-3-one.

White or almost white powder.

mp: about 180 °C.

Standard solution for the micro determination of water. *1147300.*

Commercially available standard solution for the coulometric titration of water, containing a certified content of water in a suitable solvent.

***Staphylococcus aureus* strain V8 protease, type XVII-B.** *1115800.* [66676-43-5].

Microbial extracellular proteolytic enzyme. A lyophilised powder containing 500 units to 1000 units per milligram of solid.

Starch, soluble. *1085100.* [9005-84-9].

White or almost white powder.

Prepare a 20 g/L solution in hot *water R*. The solution is at most slightly opalescent and remains fluid on cooling.

Starch iodate paper. *1085101.*

Immerse strips of filter paper in 100 mL of *iodide-free starch solution R* containing 0.1 g of *potassium iodate R*. Drain and allow to dry protected from light.

Starch iodide paper. *1085106.*

Immerse strips of filter paper in 100 mL of *starch solution R* containing 0.5 g of *potassium iodide R*. Drain and allow to dry protected from light.

Test for sensitivity. Mix 0.05 mL of *0.1 M sodium nitrite* with 4 mL of *hydrochloric acid R* and dilute to 100 mL with *water R*. Apply one drop of the solution to starch iodide paper; a blue spot appears.

Starch solution. *1085103.*

Triturate 1.0 g of *soluble starch R* with 5 mL of *water R* and whilst stirring pour the mixture into 100 mL of boiling *water R* containing 10 mg of *mercuric iodide R*.

Carry out the test for sensitivity each time the reagent is used.

Test for sensitivity. To a mixture of 1 mL of the starch solution and 20 mL of *water R*, add about 50 mg of *potassium iodide R* and 0.05 mL of *iodine solution R1*. The solution is blue.

Starch solution, iodide-free. *1085104.*

Prepare the solution as prescribed for *starch solution R* omitting the mercuric iodide. Prepare immediately before use.

Starch solution R1. *1085105.*

Mix 1 g of *soluble starch R* and a small amount of cold *water R*. Add this mixture, while stirring, to 200 mL of boiling *water R*. Add 0.25 g of *salicylic acid R* and boil for 3 min. Immediately remove from the heat and cool.

Storage: long storage is required, the solution shall be stored at 4 °C to 10 °C. A fresh starch solution shall be prepared when the end-point of the titration from blue to colourless fails to be sharp. If stored under refrigeration, the starch solution is stable for about 2 to 3 weeks.

Test for sensitivity. A mixture of 2 mL of *starch solution R1*, 20 mL of *water R*, about 50 mg of *potassium iodide R* and 0.05 mL of *iodine solution R1* is blue.

Starch solution R2. *1085107.*

Triturate 1.0 g of *soluble starch R* with 5 mL of *water R* and whilst stirring pour the mixture into 100 mL of boiling *water R*. Use a freshly prepared solution.

Test for sensitivity. To a mixture of 1 mL of the starch solution and 20 mL of *water R*, add about 50 mg of *potassium iodide R* and 0.05 mL of *iodine solution R1*. The solution is blue.

Stearic acid. $C_{18}H_{36}O_2$. (M_r 284.5). *1085200.* [57-11-4]. Octadecanoic acid.

White or almost white powder or flakes, greasy to the touch, practically insoluble in water, soluble in hot ethanol (96 per cent).

mp: about 70 °C.

Stearic acid used in the assay of total fatty acids in Saw palmetto fruit (1848) complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Saw palmetto fruit (1848)*.

Content: minimum 98 per cent, calculated by the normalisation procedure.

Stearyl alcohol. $C_{18}H_{38}O$. (M_r 270.5). *1156400.* [112-92-5]. 1-Octadecanol.

mp: about 60 °C.

Content: minimum 95 per cent.

Stigmasterol. $C_{29}H_{48}O$. (M_r 412.7). *1141400.* [83-48-7]. (22*E*)-Stigmasta-5,22-dien-3β-ol. (22*E*)-24-Ethylcholesta-5,22-dien-3β-ol.

White or almost white powder, insoluble in water.

mp: about 170 °C.

$[\alpha]_D^{22}$: about − 51, determined with a 20 g/L solution in *chloroform R*.

Streptomycin sulfate. *1085300.* [3810-74-0].
See *Streptomycin sulfate (0053)*.

Strongly acidic ion-exchange resin. *1085400.*
See *ion-exchange resin, strongly acidic R*.

Strontium carbonate. $SrCO_3$. (M_r 147.6). *1122700.* [1633-05-2].
White or almost white, crystalline powder.
Content: minimum 99.5 per cent.

Strontium chloride hexahydrate. $SrCl_2,6H_2O$. (M_r 266.6). *1167000.* [10025-70-4].
White or almost white crystals, very soluble in water.
mp: about 115 °C (loss of water) and 872 °C.

Strontium selective extraction resin. *1167100.*
Commercially available resin prepared by loading a suspension of 4,4′(5′)-di-*tert*-butylcyclohexano-18-crown-6 (crown ether) in octanol onto an inert chromatographic support. The bed density of this resin is approximately 0.35 g/mL.

Strontium-85 spiking solution. *1166800.*
Dilute *strontium-85 standard solution R* to a radioactivity concentration of approximately 10 kBq/mL with a 0.27 g/L solution of *strontium chloride hexahydrate R* in a 1.03 g/L solution of *hydrochloric acid R*.

Strontium-85 standard solution. *1166900.*
A solution of strontium-85 in the form of Sr^{2+} ions in a 51.5 g/L solution of *hydrochloric acid R*.

Styrene. C_8H_8. (M_r 104.2). *1151700.* [100-42-5].
Ethenylbenzene.
bp: about 145 °C.
Colourless, oily liquid, very slightly soluble in water.

Styrene-divinylbenzene copolymer. *1085500.*
Porous, rigid, cross-linked polymer beads. Several grades are available with different sizes of beads. The size range of the beads is specified after the name of the reagent in the tests where it is used.

Succinic acid. $C_4H_6O_4$. (M_r 118.1). *1085600.* [110-15-6].
Butanedioic acid.
White or almost white, crystalline powder or colourless crystals, soluble in water and in ethanol (96 per cent).
mp: 184 °C to 187 °C.

Sucrose. *1085700.* [57-50-1].
See *Sucrose (0204)*.

Sudan orange. $C_{16}H_{12}N_2O$. (M_r 248.3). *1110700.* [842-07-9].
Colour Index No. 12055.
1-(Phenylazo)naphthalen-2-ol. Sudan I.
Orange-red powder, practically insoluble in water, soluble in methylene chloride.
mp: about 131 °C.

Sudan red G. $C_{17}H_{14}N_2O_2$. (M_r 278.3). *1085800.*
Schultz No. 149.
Colour Index No. 12150.
Solvent Red 1. 1-[(2-Methoxyphenyl)azo]naphtalen-2-ol.
Reddish-brown powder, practically insoluble in water.
Chromatography. Thin-layer chromatography (*2.2.27*) using *silica gel G R* as the coating substance: apply 10 µL of a 0.1 g/L solution in *methylene chloride R* and develop over a path of 10 cm with the same solvent; the chromatogram shows only one principal spot.

Sulfanilamide. $C_6H_8N_2O_2S$. (M_r 172.2). *1086100.* [63-74-1].
4-Aminobenzenesulfonamide.
White or almost white powder, slightly soluble in water, freely soluble in boiling water, in acetone, in dilute acids and in solutions of the alkali hydroxides, sparingly soluble in ethanol (96 per cent) and in light petroleum.
mp: about 165 °C.

Sulfathiazole. $C_9H_9N_3O_2S_2$. (M_r 255.3). *1086300.* [72-14-0].
4-Amino-*N*-(thiazol-2-yl)benzenesulfonamide.
White or yellowish-white powder or crystals, very slightly soluble in water, soluble in acetone, slightly soluble in ethanol (96 per cent). It dissolves in dilute mineral acids and in solutions of alkali hydroxides and carbonates.
mp: about 200 °C.

Sulfamic acid. H_3NO_3S. (M_r 97.1). *1085900.* [5329-14-6].
White or almost white crystalline powder or crystals, freely soluble in water, sparingly soluble in acetone, in ethanol (96 per cent) and in methanol.
mp: about 205 °C, with decomposition.

Sulfan blue. $C_{27}H_{31}N_2NaO_6S_2$. (M_r 566.6). *1086000.* [129-17-9].
Schultz No. 769.
Colour Index No. 42045.
Acid Blue 1. Patent Blue VF. Disulfine blue. Blue VS. Sodium [[[(4-diethylamino)phenyl](2,4-disulfonatophenyl)methylene]cyclohexa-2,5-dien-1-ylidene]diethylammonium.
Violet powder, soluble in water. Dilute solutions are blue and turn yellow on the addition of concentrated hydrochloric acid.

Sulfanilic acid. $C_6H_7NO_3S$. (M_r 173.2). *1086200.* [121-57-3].
4-Aminobenzenesulfonic acid.
Colourless crystals, sparingly soluble in water, practically insoluble in ethanol (96 per cent).

Sulfanilic acid solution. *1086203.*
Dissolve 0.33 g of *sulfanilic acid R* in 75 mL of *water R* heating gently if necessary and dilute to 100 mL with *glacial acetic acid R*.

Sulfanilic acid solution R1. *1086201.*
Dissolve 0.5 g of *sulfanilic acid R* in a mixture of 75 mL of *dilute acetic acid R* and 75 mL of *water R*.

Sulfanilic acid solution, diazotised. *1086202.*
Dissolve, with warming, 0.9 g of *sulfanilic acid R* in 9 mL of *hydrochloric acid R*, and dilute to 100 mL with *water R*. Cool 10 mL of this solution in iced water and add 10 mL of an ice-cold 45 g/L solution of *sodium nitrite R*. Allow to stand at 0 °C for 15 min (if stored at this temperature, the solution is stable for 3 days) and immediately before use add 20 mL of a 100 g/L solution of *sodium carbonate R*.

Sulfomolybdic reagent R2. *1086400.*
Dissolve about 50 mg of *ammonium molybdate R* in 10 mL of *sulfuric acid R*.

Sulfomolybdic reagent R3. *1086500.*
Dissolve with heating 2.5 g of *ammonium molybdate R* in 20 mL of *water R*. Dilute 28 mL of *sulfuric acid R* in 50 mL of *water R*, then cool. Mix the two solutions and dilute to 100 mL with *water R*.
Storage: in a polyethylene container.

Sulfosalicylic acid. $C_7H_6O_6S,2H_2O$. (M_r 254.2). *1086600.* [5965-83-3]. 2-Hydroxy-5-sulfobenzoic acid.
White or almost white, crystalline powder or crystals, very soluble in water and in ethanol (96 per cent).
mp: about 109 °C.

Sulfur. *1110800.* [7704-34-9].
See *Sulfur for external use (0953)*.

Sulfur dioxide. SO_2. (M_r 64.1). *1086700.* [7446-09-5]. Sulfurous anhydride.

A colourless gas. When compressed it is a colourless liquid.

Sulfur dioxide R1. SO_2. (M_r 64.1). *1110900.* [7446-09-5].

Content: minimum 99.9 per cent *V/V*.

Sulfuric acid. H_2SO_4. (M_r 98.1). *1086800.* [7664-93-9].

Content: 95.0 per cent *m/m* to 97.0 per cent *m/m*.

Colourless, caustic liquid with an oily consistency, highly hygroscopic, miscible with water and with ethanol (96 per cent) producing intense heat.

d_{20}^{20}: 1.834 to 1.837.

A 10 g/L solution is strongly acid and gives the reactions of sulfates (*2.3.1*).

Appearance. It is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

Oxidisable substances. Pour 20 g cautiously, with cooling, into 40 mL of *water R*. Add 0.5 mL of *0.002 M potassium permanganate*. The violet colour persists for at least 5 min.

Chlorides: maximum 0.5 ppm.

Pour 10 g, carefully and while cooling, into 10 mL of *water R* and after cooling dilute to 20 mL with the same solvent. Add 0.5 mL of *silver nitrate solution R2*. Allow to stand for 2 min protected from bright light. The solution is not more opalescent than a standard prepared at the same time using a mixture of 1 mL of *chloride standard solution (5 ppm Cl) R*, 19 mL of *water R* and 0.5 mL of *silver nitrate solution R2*.

Nitrates: maximum 0.5 ppm.

Pour 50 g or 27.2 mL, carefully and while cooling, into 15 mL of *water R*. Add 0.2 mL of a freshly prepared 50 g/L solution of *brucine R* in *glacial acetic acid R*. After 5 min any colour is less intense than that of a reference mixture prepared in the same manner and containing 12.5 mL of *water R*, 50 g of *nitrogen-free sulfuric acid R*, 2.5 mL of *nitrate standard solution (10 ppm NO_3) R* and 0.2 mL of a 50 g/L solution of *brucine R* in *glacial acetic acid R*.

Ammonium: maximum 2 ppm.

Pour 2.5 g, carefully and while cooling, into *water R* and dilute to 20 mL with the same solvent. Cool, and add dropwise 10 mL of a 200 g/L solution of *sodium hydroxide R*, followed by 1 mL of *alkaline potassium tetraiodomercurate solution R*. The colour of the solution is less intense than that of a mixture of 5 mL of *ammonium standard solution (1 ppm NH_4) R*, 15 mL of *water R*, 10 mL of a 200 g/L solution of *sodium hydroxide R* and 1 mL of *alkaline potassium tetraiodomercurate solution R*.

Arsenic (*2.4.2, Method A*): maximum 0.02 ppm.

To 50 g add 3 mL of *nitric acid R* and evaporate carefully until the volume is reduced to about 10 mL. Cool, add to the residue 20 mL of *water R* and concentrate to 5 mL. Prepare the standard using 1.0 mL of *arsenic standard solution (1 ppm As) R*.

Iron (*2.4.9*): maximum 1 ppm.

Dissolve the residue on ignition with slight heating in 1 mL of *dilute hydrochloric acid R* and dilute to 50.0 mL with *water R*. Dilute 5 mL of this solution to 10 mL with *water R*.

Heavy metals (*2.4.8*): maximum 2 ppm.

Dilute 10 mL of the solution obtained in the test for iron to 20 mL with *water R*. 12 mL of the solution complies with test A. Prepare the reference solution using *lead standard solution (2 ppm Pb) R*.

Residue on ignition: maximum 0.001 per cent, determined on 100 g by evaporating cautiously in a small crucible over a naked flame and igniting the residue to redness.

Assay. Weigh accurately a ground-glass-stoppered flask containing 30 mL of *water R*, introduce 0.8 mL of the sulfuric acid, cool and weigh again. Titrate with *1 M sodium hydroxide*, using 0.1 mL of *methyl red solution R* as indicator.

1 mL of *1 M sodium hydroxide* is equivalent to 49.04 mg of H_2SO_4.

Storage: in a ground-glass-stoppered container made of glass or other inert material.

Sulfuric acid, alcoholic, 2.5 M. *1086801.*

Carefully and with constant cooling, stir 14 mL of *sulfuric acid R* into 60 mL of *anhydrous ethanol R*. Allow to cool and dilute to 100 mL with *anhydrous ethanol R*. Prepare immediately before use.

Sulfuric acid, alcoholic, 0.25 M. *1086802.*

Dilute 10 mL of *2.5 M alcoholic sulfuric acid R* to 100 mL with *anhydrous ethanol R*. Prepare immediately before use.

Sulfuric acid, alcoholic solution of. *1086803.*

Carefully and with constant cooling, stir 20 mL of *sulfuric acid R* into 60 mL of *ethanol (96 per cent) R*. Allow to cool and dilute to 100 mL with *ethanol (96 per cent) R*. Prepare immediately before use.

Sulfuric acid, dilute. *1086804.*

Contains 98 g/L of H_2SO_4.

Add 5.5 mL of *sulfuric acid R* to 60 mL of *water R*, allow to cool and dilute to 100 mL with the same solvent.

Assay. Into a ground-glass-stoppered flask containing 30 mL of *water R*, introduce 10.0 mL of the dilute sulfuric acid. Titrate with *1 M sodium hydroxide*, using 0.1 mL of *methyl red solution R* as indicator.

1 mL of *1 M sodium hydroxide* is equivalent to 49.04 mg of H_2SO_4.

Sulfuric acid-formaldehyde reagent. *1086805.*

Mix 2 mL of *formaldehyde solution R* with 100 mL of *sulfuric acid R*.

Sulfuric acid, heavy metal-free. *1086807.*

Complies with the requirements prescribed for *sulfuric acid R* with the following maximum contents of heavy metals.

As: 0.005 ppm.

Cd: 0.002 ppm.

Cu: 0.001 ppm.

Fe: 0.05 ppm.

Hg: 0.005 ppm.

Ni: 0.002 ppm.

Pb: 0.001 ppm.

Zn: 0.005 ppm.

Sulfuric acid, nitrogen-free. *1086806.*

Complies with the requirements prescribed for *sulfuric acid R* with the following additional test.

Nitrates. To 5 mL of *water R* add carefully 45 mL of the sulfuric acid, allow to cool to 40 °C and add 8 mg of *diphenylbenzidine R*. The solution is faint pink or very pale blue.

Sulfuric acid, nitrogen-free R1. *1086808.*

Complies with the requirements prescribed for *nitrogen-free sulfuric acid R*.

Content: 95.0 per cent *m/m* to 95.5 per cent *m/m*.

Sunflower oil. *1086900.*

See *Sunflower oil, refined (1371)*.

Swertiamarin. $C_{16}H_{22}O_{10}$. (M_r 374.3). *1163600.* [17388-39-5]. Swertiamaroside. (4*R*,5*R*,6*S*)-5-Ethenyl-6-(β-D-glucopyranosyloxy)-4a-hydroxy-4,4a,5,6-tetrahydro-1*H*,3*H*-pyrano[3,4-*c*]pyran-1-one.

Tagatose. $C_6H_{12}O_6$. (M_r 180.16). *1111000.* [87-81-0]. D-*lyxo*-Hexulose.

White or almost white powder.

$[\alpha]_D^{20}$: – 2.3 determined on a 21.9 g/L solution.

mp: 134 °C to 135 °C.

Talc. *1087000.* [14807-96-6].

See *Talc (0438).*

Tannic acid. *1087100.* [1401-55-4].

Yellowish or light-brown, glistening scales or amorphous powder, very soluble in water, freely soluble in ethanol (96 per cent), soluble in acetone.

Storage: protected from light.

Tartaric acid. *1087200.* [87-69-4].

See *Tartaric acid (0460).*

Taxifolin. $C_{15}H_{12}O_7$. (M_r 304.3). *1151800.* [480-18-2]. (2*R*,3*R*)-2-(3,4-Dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydro-4*H*-1-benzopyran-4-one.

White or almost white powder, slightly soluble in anhydrous ethanol.

Absorbance (*2.2.25*). A solution in *anhydrous ethanol R* shows an absorption maximum at 290 nm.

Tecnazene. $C_6HCl_4NO_2$. (M_r 260.9). *1132400.* [117-18-0].

bp: about 304 °C.

mp: 99 °C to 100 °C.

A suitable certified reference solution (10 ng/µl in cyclohexane) may be used.

α-Terpinene. $C_{10}H_{16}$. (M_r 136.2). *1140300.* [99-86-5]. 1-Isopropyl-4-methylcyclohexa-1,3-diene.

Clear, almost colourless liquid.

d_4^{20}: about 0.837.

n_D^{20}: about 1.478.

bp: about 174 °C.

α-Terpinene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Tea tree oil (1837).*

Content: minimum 90 per cent, calculated by the normalisation procedure.

γ-Terpinene. $C_{10}H_{16}$. (M_r 136.2). *1115900.* [99-85-4]. 1-Isopropyl-4-methylcyclohexa-1,4-diene.

Oily liquid.

γ-Terpinene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*

Test solution. The substance to be examined.

Content: minimum 93.0 per cent, calculated by the normalisation procedure.

Terpinen-4-ol. $C_{10}H_{18}O$. (M_r 154.2). *1116000.* [562-74-3]. 4-Methyl-1-(1-methylethyl)cyclohex-3-en-1-ol. *p*-Menth-1-en-4-ol.

Oily, colourless liquid.

Terpinen-4-ol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Lavender oil (1338).*

Test solution. The substance to be examined.

Content: minimum 90.0 per cent, calculated by the normalisation procedure.

α-Terpineol. $C_{10}H_{18}O$. (M_r 154.2). *1087300.* [98-55-5]. (*RS*)-2-(4-Methylcyclohex-3-enyl)-2-propanol.

Colourless crystals, practically insoluble in water, soluble in ethanol (96 per cent).

d_{20}^{20}: about 0.935.

n_D^{20}: about 1.483.

$[\alpha]_D^{20}$: about 92.5.

mp: about 35 °C.

It may contain 1 to 3 per cent of β-terpineol.

α-Terpineol used in gas chromatography complies with the following test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Anise oil (0804).*

Test solution. A 100 g/L solution in *hexane R.*

Content: minimum 97.0 per cent, calculated by the normalisation procedure.

Terpinolene. $C_{10}H_{16}$. (M_r 136.2). *1140400.* [586-62-9]. *p*-Mentha-1,4(8)-diene. 4-Isopropylidene-1-methylcyclohexene.

Clear, almost colourless liquid.

d_4^{20}: about 0.863.

n_D^{20}: about 1.488.

bp: about 184 °C.

Terpinolene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Tea tree oil (1837).*

Content: minimum 90 per cent, calculated by the normalisation procedure.

Testosterone. *1116100.* [58-22-0].

See *Testosterone (1373).*

Testosterone propionate. *1087400.* [57-85-2].

See *Testosterone propionate (0297).*

1,2,3,4-Tetra-*O*-acetyl-β-D-glucopyranose. $C_{14}H_{20}O_{10}$. (M_r 348.3). *1172600.* [13100-46-4].

White or almost white powder, soluble in water with gentle heating.

$[\alpha]_D^{20}$: + 11, determined on a 6 g/L solution in *chloroform R.*

mp: 126 °C to 128 °C.

1,3,4,6-Tetra-*O*-acetyl-β-D-mannopyranose. $C_{14}H_{20}O_{10}$. (M_r 348.3). *1174100.* [18968-05-3].

Colourless or white powder or crystals.

mp: 160 °C to 161 °C.

$[\alpha]_D^{20}$: – 68, determined on a 7 g/L solution in *methylene chloride R.*

Tetrabutylammonium bromide. $C_{16}H_{36}BrN$. (M_r 322.4). *1087500.* [1643-19-2].

White or almost white crystals.

mp: 102 °C to 104 °C.

Tetrabutylammonium dihydrogen phosphate. $C_{16}H_{38}NO_4P$. (M_r 339.5). *1087600.* [5574-97-0].

White or almost white powder, hygroscopic.

pH (*2.2.3*): about 7.5 for a 170 g/L solution.

Absorbance (*2.2.25*): about 0.10 determined at 210 nm using a 170 g/L solution.

Storage: in an airtight container.

Tetrabutylammonium hydrogen sulfate. $C_{16}H_{37}NO_4S$. (M_r 339.5). *1087700.* [32503-27-8].

Crystalline powder or colourless crystals, freely soluble in water and in methanol.

mp: 169 °C to 173 °C.

Absorbance (*2.2.25*): maximum 0.05, determined between 240 nm and 300 nm using a 50 g/L solution.

Tetrabutylammonium hydrogen sulfate R1. *1087701.*

Complies with the requirements prescribed for *tetrabutylammonium hydrogen sulfate R* with the following additional requirement.

Absorbance (*2.2.25*): maximum 0.02, determined between 215 nm and 300 nm using a 50 g/L solution.

Tetrabutylammonium hydroxide. $C_{16}H_{37}NO,30H_2O$. (M_r 800). *1087800.* [2052-49-5].

Content: minimum 98.0 per cent of $C_{16}H_{37}NO,30H_2O$.

White or almost white crystals, soluble in water.

Assay. Dissolve 1.000 g in 100 mL of *water R*. Titrate immediately with *0.1 M hydrochloric acid* determining the end-point potentiometrically (*2.2.20*). Carry out a blank titration.

1 mL of *0.1 M hydrochloric acid* is equivalent to 80.0 mg $C_{16}H_{37}NO,30H_2O$.

Tetrabutylammonium hydroxide solution (104 g/L). *1087801.*

A solution containing 104 g/L of $C_{16}H_{37}NO$ (M_r 259.5), prepared by dilution of a suitable reagent grade.

Tetrabutylammonium hydroxide solution (400 g/L). *1087802.*

A solution containing 400 g/L of $C_{16}H_{37}NO$ (M_r 259.5) of a suitable grade.

Tetrabutylammonium iodide. $C_{16}H_{36}IN$. (M_r 369.4). *1087900.* [311-28-4].

Content: minimum 98.0 per cent.

White or slightly coloured, crystalline powder or crystals, soluble in ethanol (96 per cent).

Sulfated ash (*2.4.14*): maximum 0.02 per cent.

Assay. Dissolve 1.200 g in 30 mL of *water R*. Add 50.0 mL of *0.1 M silver nitrate* and 5 mL of *dilute nitric acid R*. Titrate the excess of silver nitrate with *0.1 M ammonium thiocyanate*, using 2 mL of *ferric ammonium sulfate solution R2* as indicator.

1 mL of *0.1 M silver nitrate* is equivalent to 36.94 mg of $C_{16}H_{36}IN$.

Tetrachloroethane. $C_2H_2Cl_4$. (M_r 167.9). *1088000.* [79-34-5]. 1,1,2,2-Tetrachloroethane.

Clear, colourless liquid, slightly soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 1.59.

n_D^{20}: about 1.495.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 145 °C and 147 °C.

Tetrachlorvinphos. $C_{10}H_9Cl_4O_4P$. (M_r 366.0). *1132500.* [22248-79-9].

mp: about 95 °C.

A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

Tetracos-15-enoic acid methyl ester. $C_{25}H_{48}O_2$. (M_r 380.7). *1144800.* [2733-88-2]. 15-Tetracosaenoic acid methyl ester. Methyl tetracos-15-enoate. Nervonic acid methyl ester.

Content: minimum 99.0 per cent, determined by gas chromatography.

Liquid.

Tetracycline hydrochloride. *1147000.*

See *Tetracycline hydrochloride (0210).*

Tetradecane. $C_{14}H_{30}$. (M_r 198.4). *1088200.* [629-59-4]. *n*-Tetradecane.

Content: minimum 99.5 per cent *m/m*.

A colourless liquid.

d_{20}^{20}: about 0.76.

n_D^{20}: about 1.429.

bp: about 252 °C.

mp: about – 5 °C.

Tetradecylammonium bromide. $C_{40}H_{84}BrN$. (M_r 659). *1088300.* [14937-42-9]. Tetrakis(decyl)ammonium bromide.

White or slightly coloured, crystalline powder or crystals.

mp: 88 °C to 89 °C.

Tetraethylammonium hydrogen sulfate. $C_8H_{21}NO_4S$. (M_r 227.3). *1116200.* [16873-13-5].

Hygroscopic powder.

mp: about 245 °C.

Tetraethylammonium hydroxide solution. $C_8H_{21}NO$. (M_r 147.3). *1100300.* [77-98-5].

A 200 g/L solution.

Colourless liquid, strongly alkaline.

d_{20}^{20}: about 1.01.

n_D^{20}: about 1.372.

HPLC grade.

Tetraethylene pentamine. $C_8H_{23}N_5$. (M_r 189.3). *1102000.* [112-57-2]. 3,6,9-Triazaundecan-1,11-diamine.

Colourless liquid, soluble in acetone.

n_D^{20}: about1.506.

Storage: protected from humidity and heat.

Tetraheptylammonium bromide. $C_{28}H_{60}BrN$. (M_r 490.7). *1088400.* [4368-51-8].

White or slightly coloured, crystalline powder or crystals.

mp: 89 °C to 91 °C.

Tetrahexylammonium bromide. $C_{24}H_{52}BrN$. (M_r 434.6). *1152500.* [4328-13-6]. *N,N,N*-Trihexylhexan-1-aminium bromide.

White or almost white, crystalline powder, hygroscopic.

mp: about 100 °C.

Tetrahexylammonium hydrogen sulfate. $C_{24}H_{53}NO_4S$. (M_r 451.8). *1116300.* [32503-34-7]. *N,N,N*-Trihexylhexan-1-aminium hydrogen sulfate.

White or almost white crystals.

mp: 100 °C to 102 °C.

Tetrahydrofuran. C_4H_8O. (M_r 72.1). *1088500.* [109-99-9]. Tetramethylene oxide.

Clear, colourless, flammable liquid, miscible with water, with ethanol (96 per cent).

d_{20}^{20}: about 0.89.

Do not distil if the tetrahydrofuran does not comply with the test for peroxides.

Peroxides. Place 8 mL of *potassium iodide and starch solution R* in a 12 mL ground-glass-stoppered cylinder about 1.5 cm in diameter. Fill completely with the substance to be examined, shake vigorously and allow to stand protected from light for 30 min. No colour is produced.

Tetrahydrofuran used in spectrophotometry complies with the following additional test.

Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 20 per cent at 255 nm, 80 per cent at 270 nm, 98 per cent at 310 nm.

Tetrahydrofuran for chromatography R. *1147100.*

Complies with the requirements prescribed for *tetrahydrofuran R* with the following additional requirements:

d_4^{20} = 0.8892.

bp: about 66 °C.

Content: minimum 99.8 per cent of C_4H_8O.

α-Tetralone. $C_{10}H_{10}O$. (M_r 146.2). *1171800.* [529-34-0]. 1-Oxotetraline. 3,4-Dihydronaphthalen-1(2*H*)-one.

bp: about 115 °C.

mp: about 5 °C.

Tetramethylammonium bromide. $C_4H_{12}BrN$. (M_r 154.1). *1156600.* [64-20-0]. *N,N,N*-Trimethylmethanaminium bromide.

White or slightly yellow crystals, freely soluble in water.

mp: about 285 °C, with decomposition.

Tetramethylammonium chloride. $C_4H_{12}ClN$. (M_r 109.6). *1100400.* [75-57-0].

Colourless crystals, soluble in water and in ethanol (96 per cent).

mp: about 300 °C, with decomposition.

Tetramethylammonium hydrogen sulfate. $C_4H_{13}NO_4S$. (M_r 171.2). *1116400.* [80526-82-5].

Hygroscopic powder.

mp: about 295 °C.

Tetramethylammonium hydroxide. $C_4H_{13}NO,5H_2O$. (M_r 181.2). *1122800.* [10424-65-4]. Tetramethylammonium hydroxide pentahydrate.

Suitable grade for HPLC.

Tetramethylammonium hydroxide solution. *1088600.* [75-59-2].

Content: minimum 10.0 per cent *m/m* of $C_4H_{13}NO$. (M_r 91.2).

Clear, colourless or very pale yellow liquid, miscible with water and with ethanol (96 per cent).

Assay. To 1.000 g add 50 mL of *water R* and titrate with *0.05 M sulfuric acid,* using 0.1 mL of *methyl red solution R* as indicator.

1 mL of *0.05 M sulfuric acid* is equivalent to 9.12 mg of $C_4H_{13}NO$.

Tetramethylammonium hydroxide solution, dilute. *1088601.*

Dilute 10 mL of *tetramethylammonium hydroxide solution R* to 100 mL with *aldehyde-free alcohol R*. Prepare immediately before use.

Tetramethylbenzidine. $C_{16}H_{20}N_2$. (M_r 240.3). *1132600.* [54827-17-7]. 3,3′,5,5′-Tetramethylbiphenyl-4,4′-diamine.

Powder, practically insoluble in water, very soluble in methanol.

mp: about 169 °C.

1,1,3,3-Tetramethylbutylamine. $C_8H_{19}N$. (M_r 129.3). *1141500.* [107-45-9]. 2-Amino-2,4,4-trimethylpentane.

Clear, colourless liquid.

d_{20}^{20}: about 0.805.

n_D^{20}: about 1.424.

bp: about 140 °C.

Tetramethyldiaminodiphenylmethane. $C_{17}H_{22}N_2$. (M_r 254.4). *1088700.* [101-61-1]. 4,4′-Methylenebis-(*N,N*-dimethylaniline).

White or bluish-white crystals or leaflets, practically insoluble in water, slightly soluble in ethanol (96 per cent), soluble in mineral acids.

mp: about 90 °C.

Tetramethyldiaminodiphenylmethane reagent. *1088701.*

Solution A. Dissolve 2.5 g of *tetramethyldiaminodiphenylmethane R* in 10 mL of *glacial acetic acid R* and add 50 mL of *water R*.

Solution B. Dissolve 5 g of *potassium iodide R* in 100 mL of *water R*.

Solution C. Dissolve 0.30 g of *ninhydrin R* in 10 mL of *glacial acetic acid R* and add 90 mL of *water R*.

Mix solution A, solution B and 1.5 mL of solution C.

Tetramethylethylenediamine. $C_6H_{16}N_2$. (M_r 116.2). *1088800.* [110-18-9]. *N,N,N′,N′*-Tetramethylethylenediamine.

Colourless liquid, miscible with water and with ethanol (96 per cent).

d_{20}^{20}: about 0.78.

n_D^{20}: about 1.418.

bp: about 121 °C.

Tetramethylsilane. $C_4H_{12}Si$. (M_r 88.2). *1088900.* [75-76-3]. TMS.

Clear, colourless liquid, very slightly soluble in water, soluble in acetone and in ethanol (96 per cent).

d_{20}^{20}: about 0.64.

n_D^{20}: about 1.358.

bp: about 26 °C.

Tetramethylsilane used in nuclear magnetic resonance spectrometry complies with the following additional test.

In the nuclear magnetic resonance spectrum of an approximately 10 per cent *V/V* solution of the tetramethylsilane in *deuterated chloroform R*, the intensity of any foreign signal, excluding those due to spinning side bands and to chloroform, is not greater than the intensity of the C-13 satellite signals located at a distance of 59.1 Hz on each side of the principal signal of tetramethylsilane.

Tetrandrine. $C_{38}H_{42}N_2O_6$. (M_r 623). *1178500.* [518-34-3].

Tetrapropylammonium chloride. $C_{12}H_{28}ClN$. (M_r 221.8). *1151900.* [5810-42-4].

White or almost white, crystalline powder, sparingly soluble in water.

mp: about 241 °C.

Tetrazolium blue. $C_{40}H_{32}Cl_2N_8O_2$. (M_r 728). *1089000.* [1871-22-3]. 3,3′-(3,3′-Dimethoxy[1,1′-biphenyl]-4,4′-diyl)bis[2,5-diphenyl-2*H*-tetrazolium] dichloride.

Yellow crystals, slightly soluble in water, freely soluble in ethanol (96 per cent) and in methanol, practically insoluble in acetone.

mp: about 245 °C, with decomposition.

Tetrazolium bromide. $C_{18}H_{16}BrN_5S$. (M_r 414.3). *1152700.* [298-93-1]. 3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide. MTT.

Tetrazolium salt. $C_{20}H_{17}N_5O_6S_2$. (M_r 487.5). *1174200.* [138169-43-4]. 5-(3-Carboxymethoxyphenyl)-3-(4,5-dimethylthiazol-2-yl)-2-(4-sulfophenyl)-2*H*-tetrazolium, inner salt. MTS.

Thallous sulfate. Tl_2SO_4. (M_r 504.8). *1089100.* [7446-18-6]. Dithallium sulfate.

White or almost white, rhomboid prisms, slightly soluble in water, practically insoluble in ethanol (96 per cent).

Thebaine. $C_{19}H_{21}NO_3$. (M_r 311.4). *1089200.* [115-37-7]. (5*R*,9*R*,13*S*)-4,5-Epoxy-3,6-dimethoxy-9a-methylmorphina-6,8-diene.

White or pale yellow, crystalline powder, very slightly soluble in water, soluble in hot anhydrous ethanol and in toluene.

mp: about 193 °C.

Chromatography (*2.2.27*). Thin-layer chromatography (*2.2.27*) as prescribed in identification test B in the monograph *Raw opium (0777)*: apply to the plate as a band (20 mm × 3 mm) 20 µL of a 0.5 g/L solution; the chromatogram shows an orange-red or red principal band with an R_F of about 0.5.

Theobromine. *1138800.* [83-67-0].

See *Theobromine (0298).*

Theophylline. *1089300.* [58-55-9].

See *Theophylline (0299).*

Thiamazole. $C_4H_6N_2S$. (M_r 114.2). *1089400.* [60-56-0]. Methimazole. 1-Methyl-1*H*-imidazole-2-thiol.

White or almost white, crystalline powder, freely soluble in water, soluble in ethanol (96 per cent) and in methylene chloride.

mp: about 145 °C.

2-(2-Thienyl)acetic acid. $C_6H_6O_2S$. (M_r 142.1). *1089500.* [1918-77-0].

Brown powder.

mp: about 65 °C.

Thioacetamide. C_2H_5NS. (M_r 75.1). *1089600.* [62-55-5].

Crystalline powder or colourless crystals, freely soluble in water and in ethanol (96 per cent).

mp: about 113 °C.

Thioacetamide reagent. *1089601.*

To 0.2 mL of *thioacetamide solution R* add 1 mL of a mixture of 5 mL of *water R*, 15 mL of *1 M sodium hydroxide* and 20 mL of *glycerol (85 per cent) R*. Heat in a water-bath for 20 s. Prepare immediately before use.

Thioacetamide solution. *1089602.*

A 40 g/L solution.

Thiobarbituric acid. $C_4H_4N_2O_2S$. (M_r 144.2). *1111200.* [504-17-6]. 4,6-Dihydroxy-2-sulfanylpyrimidine.

Thiodiethylene glycol. $C_4H_{10}O_2S$. (M_r 122.2). *1122900.* [111-48-8]. Di(2-hydroxyethyl) sulfide.

Colourless or yellow, viscous liquid.

Content: minimum 99.0 per cent.

d_{20}^{20}: about 1.18.

Thioglycollic acid. $C_2H_4O_2S$. (M_r 92.1). *1089700.* [68-11-1]. 2-Mercaptoacetic acid.

Colourless liquid, miscible with water, soluble in ethanol (96 per cent).

Thiomalic acid. $C_4H_6O_4S$. (M_r 150.2). *1161600.* [70-49-5]. (2*RS*)-2-Sulfanylbutanedioic acid.

mp: 150 °C to 152 °C.

Thiomersal. $C_9H_9HgNaO_2S$. (M_r 404.8). *1089800.* [54-64-8]. Sodium mercurothiolate. Sodium 2-[(ethylmercurio)thio]benzoate.

Light, yellowish-white, crystalline powder, very soluble in water, freely soluble in ethanol (96 per cent).

Thiourea. CH_4N_2S. (M_r 76.1). *1089900.* [62-56-6].

White or almost white, crystalline powder or crystals, soluble in water and in ethanol (96 per cent).

mp: about 178 °C.

Threonine. *1090000.* [72-19-5].

See *Threonine (1049).*

Thrombin, bovine. *1090200.* [9002-04-4].

A preparation of the enzyme, obtained from bovine plasma, that converts fibrinogen into fibrin.

A yellowish-white powder.

Storage: at a temperature below 0 °C.

Thrombin, human. *1090100.* [9002-04-4].

Dried human thrombin. A preparation of the enzyme which converts human fibrinogen into fibrin. It is obtained from liquid human plasma and may be prepared by precipitation with suitable salts and organic solvents under controlled conditions of pH, ionic strength and temperature.

Yellowish-white powder, freely soluble in a 9 g/L solution of sodium chloride forming a cloudy, pale yellow solution.

Storage: in a sealed, sterile container under nitrogen, protected from light, at a temperature below 25 °C.

Thrombin solution, human. *1090101.*

Reconstitute *human thrombin R* as directed by the manufacturer and dilute with *tris(hydroxymethyl)aminomethane sodium chloride buffer solution pH 7.4 R* to 5 IU/mL.

Thrombin solution, human R1. *1090102.*

Reconstitute *human thrombin R* as directed by the manufacturer and dilute to 2.5 IU/mL with *phosphate buffer solution pH 6.5 R*.

Thromboplastin. *1090300.*

A preparation containing the membrane glycoprotein tissue factor and phospholipid, either purified from animal brain (usually rabbit) or human placenta or manufactured using recombinant DNA technology with added phospholipid. The preparation is formulated for routine use in the prothrombin time test and may contain calcium.

Thujone. $C_{10}H_{16}O$. (M_r 152.2). *1116500.* [76231-76-0]. 4-Methyl-1-(1-methylethyl)bicyclo[3.1.0]hexan-3-one.

Colourless or almost colourless liquid, practically insoluble in water, soluble in ethanol (96 per cent) and in many other organic solvents.

Thymidine. $C_{10}H_{14}N_2O_5$. (M_r 242.2). *1158900.* 1-(2-Deoxy-β-D-*erythro*-pentofuranosyl)-5-methylpyrimidine-2,4(1*H*,3*H*)-dione.

Needles, soluble in water, in hot ethanol (96 per cent) and in glacial acetic acid.

Thymine. $C_5H_6N_2O_2$. (M_r 126.1). *1090400.* [65-71-4]. 5-Methylpyrimidine-2,4(1*H*,3*H*)-dione.

Short needles or plates, slightly soluble in cold water, soluble in hot water. It dissolves in dilute solution of alkali hydroxides.

Thymol. *1090500.* [89-83-8]. See *Thymol (0791).*

Thymol used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Peppermint oil (0405).*

Test solution. Dissolve 0.1 g in about 10 mL of *acetone R*.

Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Thymol blue. $C_{27}H_{30}O_5S$. (M_r 466.6). *1090600.* [76-61-9]. Thymolsulfonphthalein. 4,4′-(3*H*-2,1-Benzoxathiol-3-ylidene)bis(2-isopropyl-5-methylphenol) *S,S*-dioxide.

Brownish-green or greenish-blue, crystalline powder, slightly soluble in water, soluble in ethanol (96 per cent) and in dilute solutions of alkali hydroxides.

Thymol blue solution. *1090601.*

Dissolve 0.1 g of *thymol blue R* in a mixture of 2.15 mL of *0.1 M sodium hydroxide* and 20 mL of *ethanol (96 per cent) R* and dilute to 100 mL with *water R*.

Test for sensitivity. To 0.1 mL of the thymol blue solution add 100 mL of *carbon dioxide-free water R* and 0.2 mL of *0.02 M sodium hydroxide*. The solution is blue. Not more than 0.15 mL of *0.02 M hydrochloric acid* is required to change the colour to yellow.

Colour change: pH 1.2 (red) to pH 2.8 (yellow); pH 8.0 (olive-green) to pH 9.6 (blue).

Thymolphthalein. $C_{28}H_{30}O_4$. (M_r 430.5). *1090700.* [125-20-2]. 3,3-bis(4-Hydroxy-5-isopropyl-2-methylphenyl)-3*H*-isobenzofuran-1-one.

White or yellowish-white powder, practically insoluble in water, soluble in ethanol (96 per cent) and in dilute solutions of alkali hydroxides.

Thymolphthalein solution. *1090701.*

A 1 g/L solution in *ethanol (96 per cent) R*.

Test for sensitivity. To 0.2 mL of the thymolphthalein solution add 100 mL of *carbon dioxide-free water R*. The solution is colourless. Not more than 0.05 mL of *0.1 M sodium hydroxide* is required to change the colour to blue.

Colour change: pH 9.3 (colourless) to pH 10.5 (blue).

Tin. Sn. (A_r 118.7). *1090800.* [7440-31-5].

Silvery-white granules, soluble in hydrochloric acid with release of hydrogen.

Arsenic (*2.4.2, Method A*): maximum 10 ppm, determined on 0.1 g.

Titan yellow. $C_{28}H_{19}N_5Na_2O_6S_4$. ($M_r$ 696). *1090900.* [1829-00-1].

Schultz No. 280.

Colour Index No. 19540.

Thiazol yellow. Disodium 2,2′-[(1-triazene-1,3-diyl)di-4,1-phenylene]bis-[6-methylbenzothiazole-7-sulfonate].

A yellowish-brown powder, freely soluble in water and in ethanol (96 per cent).

Titan yellow paper. *1090901.*

Immerse strips of filter paper in *titan yellow solution R* and leave for a few minutes. Allow to dry at room temperature.

Titan yellow solution. *1090902.*

A 0.5 g/L solution.

Test for sensitivity. To 0.1 mL of the titan yellow solution add 10 mL of *water R*, 0.2 mL of *magnesium standard solution (10 ppm Mg) R* and 1.0 mL of *1 M sodium hydroxide*. A distinct pink colour is visible by comparison with a reference solution prepared in a similar manner omitting the magnesium.

Titanium. Ti. (A_r 47.88). *1091000.* [7440-32-6].

Content: minimum 99 per cent.

Metal powder, fine wire (diameter not more than 0.5 mm), sponge.

mp: about 1668 °C.

Density: about 4.507 g/cm^3.

Titanium dioxide. *1117900.* [13463-67-7].

See *Titanium dioxide (0150)*.

Titanium trichloride. $TiCl_3$. (M_r 154.3). *1091200.* [7705-07-9].

Titanium(III) chloride.

Reddish-violet crystals, deliquescent, soluble in water and in ethanol (96 per cent).

mp: about 440 °C.

Storage: in an airtight container.

Titanium trichloride solution. *1091201.*

d_{20}^{20}: about 1.19.

A 150 g/L solution in hydrochloric acid (100 g/L HCl).

Titanium trichloride-sulfuric acid reagent. *1091202.*

Carefully mix 20 mL of *titanium trichloride solution R* with 13 mL of *sulfuric acid R*. Add sufficient *strong hydrogen peroxide solution R* to give a yellow colour. Heat until white fumes are evolved. Allow to cool. Dilute with *water R* and repeat the evaporation and addition of *water R* until a colourless solution is obtained. Dilute to 100 mL with *water R*.

TLC aluminium oxide G plate. *1165200.*

Support of metal, glass or plastic, coated with a layer of aluminium oxide (particle size 5-40 µm) containing about 10 per cent of calcium sulfate hemihydrate as a binder.

TLC octadecylsilyl silica gel plate. *1148600.*

Support of glass, metal or plastic coated with a layer of octadecylsilyl silica gel. The plate may contain an organic binder.

TLC octadecylsilyl silica gel F_{254} plate R. *1146600.*

Support of glass, metal or plastic coated with a layer of octadecylsilyl silica gel.

It contains a fluorescent indicator having a maximum absorbance in ultraviolet light at 254 nm.

TLC performance test solution. *1116600.*

Prepare a mixture of 1.0 mL of each of the following solutions and dilute to 10.0 mL with *acetone R*: a 0.5 g/L solution of *Sudan red G R* in *toluene R*, a 0.5 g/L solution of *methyl orange R* in *ethanol R* prepared immediately before use, a 0.5 g/L solution of *bromocresol green R* in *acetone R* and a 0.25 g/L solution of *methyl red R* in *acetone R*.

TLC silica gel plate. *1116700.*

Support of glass, metal or plastic, coated with a layer of silica gel of a suitable thickness and particle size (usually 2 µm to 10 µm for fine particle size [High Performance Thin-Layer Chromatography, HPTLC] plates and 5 µm to 40 µm for normal TLC plates). If necessary, the particle size is indicated after the name of the reagent in the tests where it is used.

The plate may contain an organic binder.

Chromatographic separation. Apply to the plate an appropriate volume (10 µL for a normal TLC plate and 1 µL to 2 µL for a fine particle size plate) of *TLC performance test solution R*. Develop over a pathlength two-thirds of the plate height, using a mixture of 20 volumes of *methanol R* and 80 volumes of *toluene R*. The plate is not satisfactory, unless the chromatogram shows four clearly separated spots, the spot of bromocresol green with an R_F value less than 0.15, the spot of methyl orange with an R_F value in the range of 0.1 to 0.25, the spot of methyl red with an R_F value in the range of 0.35 to 0.55 and the spot of Sudan red G with an R_F value in the range of 0.75 to 0.98.

TLC silica gel F_{254} plate. *1116800.*

Complies with the requirements prescribed for *TLC silica gel plate R* with the following modification.

It contains a fluorescent indicator having a maximum absorbance at 254 nm.

Fluorescence suppression. Apply separately to the plate at five points increasing volumes (1 µL to 10 µL for normal TLC plates and 0.2 µL to 2 µL for fine particle size plates) of a 1 g/L solution of *benzoic acid R* in a mixture of 15 volumes of *anhydrous ethanol R* and 85 volumes of *cyclohexane R*. Develop over a pathlength half of the plate height with the same mixture of solvents. After evaporating the solvents examine the chromatogram in ultraviolet light at 254 nm. For normal TLC plates the benzoic acid appears as dark spots on a fluorescent background approximately in the middle of the chromatogram for quantities of 2 µg and greater. For fine particle size plates the benzoic acid appears as dark spots on a fluorescent background approximately in the middle of the chromatogram for quantities of 0.2 µg and greater.

TLC silica gel F_{254}, silanised plate. *1117200.*

It complies with the requirements prescribed for *TLC silica gel silanised plate R* with the following modification.

It contains a fluorescent indicator having a maximum absorbance at 254 nm.

TLC silica gel G plate. *1116900.*

Complies with the requirements prescribed for *TLC silica gel plate R* with the following modification.

It contains calcium sulfate hemihydrate as binder.

TLC silica gel GF_{254} plate. *1117000.*

Complies with the requirements prescribed for *TLC silica gel plate R* with the following modifications.

It contains calcium sulfate hemihydrate as binder and a fluorescent indicator having a maximum absorbance at 254 nm.

Fluorescence suppression. Complies with the test prescribed for *TLC silica gel F_{254} plate R*.

TLC silica gel plate for aminopolyether test. *1172700.*

Immerse a *TLC silica gel plate R* in *iodoplatinate reagent R1* for 5-10 s. Dry at room temperature for 12 h, protected from light.

Storage: protected from light, in an open container; use within 30 days after preparation.

TLC silica gel plate for chiral separations, octadecylsilyl. *1137700.*

Support of glass, metal or plastic, coated with a layer of octadecylsilyl silica gel, impregnated with Cu^{2+} ions and enantiomerically pure hydroxyproline. The plate may contain an organic binder.

TLC silica gel, silanised plate. *1117100.*

Support of glass, metal or plastic, coated with a layer of silanised silica gel of a suitable thickness and particle size (usually 2 µm to 10 µm for fine particle size [High Performance Thin-Layer Chromatography, HPTLC] plates and 5 µm to 40 µm for normal TLC plates). If necessary, the particle size is indicated after the name of the reagent in the tests where it is used.

The plate may contain an organic binder.

Chromatographic separation. Introduce 0.1 g each of *methyl laurate R, methyl myristate R, methyl palmitate R* and *methyl stearate R* into a 250 mL conical flask. Add 40 mL of *alcoholic potassium hydroxide solution R* and heat under a reflux condenser on a water-bath for 1 h. Allow to cool, transfer the solution to a separating funnel by means of 100 mL of *water R*, acidify (pH 2 to 3) with *dilute hydrochloric acid R* and shake with three quantitites each of 10 mL of *methylene chloride R*. Dry the combined methylene chloride extracts over *anhydrous sodium sulfate R*, filter and evaporate to dryness on a water-bath. Dissolve the residue in 50 mL of *methylene chloride R*. Examine by thin-layer chromatography (*2.2.27*), using *silanised TLC silica gel plate R*. Apply an appropriate quantity (about 10 µL for normal TLC plates and about 1 µL to 2 µL for fine particle size plates) of the methylene chloride solution at each of three separate points. Develop over a pathlength two-thirds of the plate height with a mixture of 10 volumes of *glacial acetic acid R*, 25 volumes of *water R* and 65 volumes of *dioxan R*. Dry the plate at 120 °C for 30 min. Allow to cool, spray with a 35 g/L solution of *phosphomolybdic acid R* in *2-propanol R* and heat at 150 °C until the spots become visible. Treat the plate with ammonia vapour until the background is white. The chromatograms show four clearly separated, well-defined spots.

α-Tocopherol. *1152300.* [10191-41-0].

See *all-rac-α-Tocopherol (0692).*

α-Tocopheryl acetate. *1152400.* [7695-91-2].

See *all-rac-α-Tocopheryl acetate (0439).*

***o*-Tolidine.** $C_{14}H_{16}N_2$. (M_r 212.3). *1123000.* [119-93-7]. 3,3′-Dimethylbenzidine.

Content: minimum 97.0 per cent.

Light brownish, crystalline power.

mp: about 130 °C.

***o*-Tolidine solution.** *1123001.*

Dissolve 0.16 g of *o-tolidine R* in 30.0 mL of *glacial acetic acid R*, add 1.0 g of *potassium iodide R* and dilute to 500.0 mL with *water R*.

Toluene. C_7H_8. (M_r 92.1). *1091300.* [108-88-3]. Methylbenzene.

Clear, colourless, flammable liquid, very slightly soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: 0.865 to 0.870.

bp: about 110 °C.

Toluene, sulfur-free. *1091301.*

Complies with the requirements prescribed for *toluene R* with the following additional requirements:

Sulfur compounds. To 10 mL add 1 mL of *anhydrous ethanol R* and 3 mL of *potassium plumbite solution R* and boil under a reflux condenser for 15 min. Allow to stand for 5 min. No darkening is produced in the aqueous layer.

Thiophen-related substances. Shake 2 mL with 5 mL of *isatin reagent R* for 5 min and allow to stand for 15 min. No blue colour is produced in the lower layer.

Toluenesulfonamide. $C_7H_9NO_2S$. (M_r 171.2). *1091500.* [70-55-3]. 4-Methylbenzenesulfonamide. *p*-Toluenesulfonamide.

White or almost white, crystalline powder, slightly soluble in water, soluble in ethanol (96 per cent) and in solutions of alkali hydroxides.

mp: about 136 °C.

Chromatography. Thin-layer chromatography (*2.2.27*) as prescribed in the monograph *Tolbutamide (0304)*; the chromatogram shows only one principal spot.

***o*-Toluenesulfonamide.** $C_7H_9NO_2S$. (M_r 171.2). *1091400.* [88-19-7]. 2-Methylbenzenesulfonamide.

White or almost white, crystalline powder, slightly soluble in water, soluble in ethanol (96 per cent) and in solutions of alkali hydroxides.

mp: about 156 °C.

***p*-Toluenesulfonamide.** *1091500.* [70-55-3].

See *toluenesulfonamide R.*

Toluenesulfonic acid. $C_7H_8O_3S,H_2O$. (M_r 190.2). *1091600.* [6192-52-5]. 4-Methylbenzenesulfonic acid.

Content: minimum 87.0 per cent of $C_7H_8O_3S$.

White or almost white, crystalline powder or crystals, freely soluble in water, soluble in ethanol (96 per cent).

Toluenesulfonylurea. $C_8H_{10}N_2O_3S$. (M_r 214.2). *1177000.* [1694-06-0]. 4-Methylbenzenesulfonylurea. *p*-Toluenesulfonylurea. (4-Methylphenyl)sulfonylurea.

White or almost white, crystalline powder.

mp: 196 to 198 °C.

***o*-Toluidine.** C_7H_9N. (M_r 107.2). *1091700.* [95-53-4]. 2-Methylaniline.

Pale-yellow liquid becoming reddish-brown on exposure to air and light, slightly soluble in water, soluble in ethanol (96 per cent) and in dilute acids.

d_{20}^{20}: about 1.01.

n_D^{20}: about 1.569.

bp: about 200 °C.

Storage: in an airtight container, protected from light.

***o*-Toluidine hydrochloride.** $C_7H_{10}ClN$. (M_r 143.6). *1117300.* [636-21-5]. 2-Methylaniline hydrochloride. 2-Methylbenzenamine hydrochloride.

Content: minimum 98.0 per cent.

mp: 215 °C to 217 °C.

***p*-Toluidine.** C_7H_9N. (M_r 107.2). *1091800.* [106-49-0]. 4-Methylaniline.

Lustrous plates or flakes, slightly soluble in water, freely soluble in acetone and in ethanol (96 per cent).

mp: about 44 °C.

Toluidine blue. $C_{15}H_{16}ClN_3S$. (M_r 305.8). *1091900.* [92-31-9].

Schultz No. 1041.

Colour Index No. 52040.
Toluidine Blue O. 3-Amino-7-dimethylamino-2-methylphenothiazin-5-ium chloride.

Dark-green powder, soluble in water, slightly soluble in ethanol (96 per cent).

Tosylarginine methyl ester hydrochloride. $C_{14}H_{23}ClN_4O_4S$. (M_r 378.9). *1092000.* [1784-03-8]. *N*-Tosyl-L-arginine methyl ester hydrochloride. Methyl (*S*)-5-guanidino-2-(4-methylbenzenesulfonamido)valerate hydrochloride.

$[\alpha]_D^{20}$: – 12 to – 16, determined on a 40 g/L solution.

mp: about 145 °C.

Tosylarginine methyl ester hydrochloride solution. *1092001.*

To 98.5 mg of *tosylarginine methyl ester hydrochloride R* add 5 mL of *tris(hydroxymethyl)aminomethane buffer solution pH 8.1 R* and shake to dissolve. Add 2.5 mL of *methyl red mixed solution R* and dilute to 25.0 mL with *water R*.

Tosyl-lysyl-chloromethane hydrochloride. $C_{14}H_{22}Cl_2N_2O_3S$. (M_r 369.3). *1092100.* [4238-41-9]. *N*-Tosyl-L-lysyl-chloromethane hydrochloride. (3*S*)-7-Amino-1-chloro-3-(4-methylbenzenesulfonamido)heptan-2-one hydrochloride.

$[\alpha]_D^{20}$: – 7 to – 9, determined on a 20 g/L solution.

mp: about 155 °C, with decomposition.

$A_{1\,cm}^{1\%}$: 310 to 340, determined at 230 nm in *water R*.

Tosylphenylalanylchloromethane. $C_{17}H_{18}ClNO_3S$. (M_r 351.9). *1092200.* [402-71-1]. *N*-Tosyl-L-phenylalanylchloromethane.

$[\alpha]_D^{20}$: – 85 to – 89, determined on a 10 g/L solution in *ethanol (96 per cent) R*.

mp: about 105 °C.

$A_{1\,cm}^{1\%}$: 290 to 320, determined at 228.5 nm in *ethanol (96 per cent) R*.

Toxaphene. *1132800.* [8001-35-2].

A mixture of polychloro derivatives.

mp: 65 °C to 90 °C.

A suitable certified reference solution (10 ng/µl in iso-octane) may be used.

Tragacanth. *1092300.* [9000-65-1].

See *Tragacanth (0532)*.

Triacetin. $C_9H_{14}O_6$. (M_r 218.2). *1092400.* [102-76-1]. Propane-1,2,3-triyl triacetate. Glycerol triacetate.

Almost clear, colourless to yellowish liquid, soluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 1.16.

n_D^{20}: about 1.43.

bp: about 260 °C.

Triamcinolone. $C_{21}H_{27}FO_6$. (M_r 394.4). *1111300.* [124-94-7]. 9-Fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione.

A crystalline powder.

mp: 262 °C to 263 °C.

Triamcinolone acetonide. *1133100.* [76-25-5].

See *Triamcinolone acetonide (0533)*.

Tribromophenol. $C_6H_3Br_3O$. (M_r 330.8). *1165300.* [118-79-6]. 2,4,6-Tribromophenol.

Tributyl citrate. $C_{18}H_{32}O_7$. (M_r 360.4). *1152800.* [77-94-1]. Tributyl 2-hydroxypropane-1,2,3-tricarboxylate.

d_4^{20}: about 1.043.

n_D^{20}: about 1.445.

Trichlorethylene. *1102100.*

See *Trichloroethylene R*.

Trichloroacetic acid. $C_2HCl_3O_2$. (M_r 163.4). *1092500.* [76-03-9].

Colourless crystals or a crystalline mass, very deliquescent, very soluble in water and in ethanol (96 per cent).

Storage: in an airtight container.

Trichloroacetic acid solution. *1092501.*

Dissolve 40.0 g of *trichloroacetic acid R* in *water R* and dilute to 1000.0 mL with the same solvent. Verify the concentration by titration with *0.1 M sodium hydroxide* and adjust if necessary to 40 ± 1 g/L.

1,1,1-Trichloroethane. $C_2H_3Cl_3$. (M_r 133.4). *1092600.* [71-55-6]. Methylchloroform.

Non-flammable liquid, practically insoluble in water, soluble in acetone and in methanol.

d_{20}^{20}: about 1.34.

n_D^{20}: about 1.438.

bp: about 74 °C.

Trichloroethylene. C_2HCl_3. (M_r 131.4). *1102100.* [79-01-6].

Colourless liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 1.46.

n_D^{20}: about 1.477.

Trichlorotrifluoroethane. $C_2Cl_3F_3$. (M_r 187.4). *1092700.* [76-13-1]. 1,1,2-Trichloro-1,2,2-trifluoroethane.

Colourless, volatile liquid, practically insoluble in water, miscible with acetone.

d_{20}^{20}: about 1.58.

Distillation range (*2.2.11*). Not less than 98 per cent distils between 47 °C and 48 °C.

Tricine. $C_6H_{13}NO_5$. (M_r 179.2). *1138900.* [5704–04–1]. *N*-[2-Hydroxy-1,1-bis(hydroxymethyl)ethyl]glycine.

Use electrophoresis-grade reagent.

mp: about 183 °C.

Tricosane. $C_{23}H_{48}$. (M_r 324.6). *1092800.* [638-67-5].

White or almost white crystals, practically insoluble in water, soluble in hexane.

mp: about 48 °C.

Tridocosahexaenoin. $C_{69}H_{98}O_6$. (M_r 1023.5). *1144900.* [124596-98-1]. Triglyceride of docosahexaenoic acid (C22:6). Glycerol tridocosahexaenoate. Propane-1,2,3-triyl tri-(*all-Z*)-docosa-4,7,10,13,16,19-hexaenoate.

The reagent from Nu-Chek Prep, Inc. has been found suitable.

Triethanolamine. *1092900.* [102-71-6].

See *Trolamine (1577)*.

Triethylamine. $C_6H_{15}N$. (M_r 101.2). *1093000.* [121-44-8]. *N,N*-Diethylethanamine.

Colourless liquid, slightly soluble in water at a temperature below 18.7 °C, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.727.

n_D^{20}: about 1.401.

bp: about 90 °C.

Triethylamine R1. $C_6H_{15}N$. (M_r 101.2). *1093001.* [121-44-8]. *N,N*-Diethylethanamine.

Complies with the requirements prescribed for *triethylamine R* with the following additional requirements.

Content: minimum 99.5 per cent, determined by gas chromatography.

Water: maximum 0.1 per cent.

Use freshly distilled or from a freshly opened container.

Triethylamine R2. $C_6H_{15}N$. (M_r 101.2). *1093002.* [121-44-8]. *N,N*-Diethylethanamine.

Complies with the requirements prescribed for *triethylamine R* and with the following additional requirements.

Content: minimum 99.5 per cent, determined by gas chromatography.

Water: maximum 0.2 per cent.

It is suitable for gradient elution in liquid chromatography.

Use freshly distilled or from a freshly opened container.

Triethylenediamine. $C_6H_{12}N_2$. (M_r 112.2). *1093100.* 1,4-Diazabicyclo[2.2.2]octane.

Crystals, very hygroscopic, sublimes readily at room temperature, freely soluble in water, in acetone and in anhydrous ethanol.

bp: about 174 °C.

mp: about 158 °C.

Storage: in an airtight container.

Triethyl phosphonoformate. $C_7H_{15}O_5P$. (M_r 210.2). *1132900.* [1474-78-8]. Ethyl (diethoxyphosphoryl)formate.

Colourless liquid.

$bp_{12\ mm}$: about 135 °C.

Trifluoroacetic acid. $C_2HF_3O_2$. (M_r 114.0). *1093200.* [76-05-1].

Content: minimum 99 per cent.

Liquid, miscible with acetone and with ethanol (96 per cent).

d_{20}^{20}: about 1.53.

bp: about 72 °C.

Use a grade suitable for protein sequencing.

Storage: in an airtight container.

Trifluoroacetic anhydride. $C_4F_6O_3$. (M_r 210.0). *1093300.* [407-25-0].

Colourless liquid.

d_{20}^{20}: about 1.5.

3-Trifluoromethylaniline. $C_7H_6F_3N$. (M_r 161.1). *1171900.* [98-16-8]. 3-(Trifluoromethyl)aniline. α,α,α-Trifluoro-*m*-toluidine. 3-(Trifluoromethyl)benzenamide.

Colourless liquid.

Density: 1.30 g/cm^3 (20 °C).

4-Trifluoromethylphenol. $C_7H_5F_3O$. (M_r 162.1). *1161700.* [402-45-9].

White or light yellow, crystalline solid or powder.

mp: about 46 °C.

Trigonelline hydrochloride. $C_7H_8ClNO_2$. (M_r 173.6). *1117400.* [6138-41-6]. 3-Carboxy-1-methylpyridinium chloride. Nicotinic acid *N*-methylbetaine hydrochloride.

Crystalline powder, very soluble in water, soluble in ethanol (96 per cent).

mp: about 258 °C.

Trimethylpentane. C_8H_{18}. (M_r 114.2). *1093400.* [540-84-1]. Iso-octane. 2,2,4-Trimethylpentane.

Colourless, flammable liquid, practically insoluble in water, soluble in anhydrous ethanol.

d_{20}^{20}: 0.691 to 0.696.

n_D^{20}: 1.391 to 1.393.

Distillation range (*2.2.11*). Not less than 95 per cent distils between 98 °C and 100 °C.

Trimethylpentane used in spectrophotometry complies with the following additional test.

Minimum transmittance (*2.2.25*) using *water R* as compensation liquid: 98 per cent from 250 nm to 420 nm.

Trimethylpentane R1. *1093401.*

Complies with the requirements prescribed for *trimethylpentane R* with the following modification.

Absorbance (2.2.25). Not more than 0.07 from 220 nm to 360 nm, determined using *water R* as the compensation liquid.

Trimethylpentane for chromatography. *1093402.*

Complies with the requirements prescribed for *trimethylpentane R* with the following additional requirement.

Residue on evaporation: maximum 2 mg/L.

***N,O*-bis(Trimethylsilyl)acetamide.** $C_8H_{21}NOSi_2$. (M_r 203.4). *1093600.* [10416-59-8].

Colourless liquid.

d_{20}^{20}: about 0.83.

***N*-Trimethylsilylimidazole.** $C_6H_{12}N_2Si$. (M_r 140.3). *1100500.* [18156-74-6]. 1-Trimethylsilylimidazole.

Colourless, hygroscopic liquid.

d_{20}^{20}: about 0.96.

n_D^{20}: about 1.48.

Storage: in an airtight container.

3-Trimethylsilyl-1-propanesulfonic acid, sodium salt. $C_6H_{15}NaO_3SSi$. (M_r 218.3). *1178700.* [2039-96-5]. Sodium 3-(trimethylsilyl)-1-propanesulfonate.

Beige powder.

Content: minimum 97.0 per cent.

mp: about 165 °C.

***N,O*-bis(Trimethylsilyl)trifluoroacetamide.** $C_8H_{18}F_3NOSi_2$. (M_r 257.4). *1133200.* [25561-30-2]. BSTFA.

Colourless liquid.

d_{20}^{20}: about 0.97.

n_D^{20}: about 1.38.

bp_{12mm}: about 40 °C

Trimethylsulfonium hydroxide. $C_3H_{10}OS$. (M_r 94.2). *1145000.* [17287-03-5].

d_4^{20}: about 0.81.

Trimethyltin chloride. C_3H_9ClSn. (M_r 199.3). *1170900.* [1066-45-1]. Chlorotrimethylstannane.

2,4,6-Trinitrobenzene sulfonic acid. $C_6H_3N_3O_9S,3H_2O$. (M_r 347.2). *1117500.* [2508-19-2].

White or almost white, crystalline powder, soluble in water.

mp: 190 °C to 195 °C.

Triolein. $C_{57}H_{104}O_6$. (M_r 885.4). *1168200.* [122-32-7]. Propane-1,2,3-triyl tris[(9*Z*)-octadec-9-enoate]. *sn*-Glyceryl trioleate. Glycerol trioleate. Oleyl triglyceride.

Content: minimum 99.0 per cent.

Triphenylmethanol. $C_{19}H_{16}O$. (M_r 260.3). *1093700.* [76-84-6]. Triphenylcarbinol.

Colourless crystals, practically insoluble in water, freely soluble in ethanol (96 per cent).

Triphenyltetrazolium chloride. $C_{19}H_{15}ClN_4$. (M_r 334.8). *1093800.* [298-96-4]. 2,3,5-Triphenyl-2*H*-tetrazolium chloride.

Content: minimum 98.0 per cent of $C_{19}H_{15}ClN_4$.

Pale or dull-yellow powder, soluble in water, in acetone and in ethanol (96 per cent).

mp: about 240 °C, with decomposition.

Assay. Dissolve 1.000 g in a mixture of 5 mL of *dilute nitric acid R* and 45 mL of *water R*. Add 50.0 mL of *0.1 M silver nitrate* and heat to boiling. Allow to cool, add 3 mL of *dibutyl phthalate R*, shake vigorously and titrate with *0.1 M ammonium thiocyanate*, using 2 mL of *ferric ammonium sulfate solution R2* as indicator.

1 mL of *0.1 M silver nitrate* is equivalent to 33.48 mg of $C_{19}H_{15}ClN_4$.

Storage: protected from light.

Triphenyltetrazolium chloride solution. *1093801.*

A 5 g/L solution in *aldehyde-free alcohol R*.

Storage: protected from light.

Triscyanoethoxypropane. $C_{12}H_{17}N_3O_3$. (M_r 251.3). *1093900.* 1,2,3-Tris(2-cyanoethoxy)propane.

Viscous, brown-yellow liquid, soluble in methanol. Used as a stationary phase in gas chromatography.

d_{20}^{20}: about 1.11.

Viscosity (*2.2.9*): about 172 mPa·s.

1,3,5-Tris[3,5-di(1,1-dimethylethyl)-4-hydroxybenzyl]-1,3,5-triazine-2,4,6(1*H*,3*H*,5*H*)-trione. $C_{48}H_{69}O_6N_3$. (M_r 784.1). *1094000.* [27676-62-6].

White or almost white, crystalline powder.

mp: 218 °C to 222 °C.

Tris[2,4-di(1,1-dimethylethyl)phenyl] phosphite. $C_{42}H_{63}O_3P$. (M_r 647). *1094100.* [31570-04-4].

White or almost white powder.

mp: 182 °C to 186 °C.

Tris(hydroxymethyl)aminomethane. *1094200.* [77-86-1].

See *Trometamol (1053)*.

Tris(hydroxymethyl)aminomethane solution. *1094201.*

A solution containing the equivalent of 24.22 g of $C_4H_{11}NO_3$ in 1000.0 mL.

Tris(hydroxymethyl)aminomethane solution R1. *1094202.*

Dissolve 60.6 mg of *tris(hydroxymethyl)aminomethane R* and 0.234 g of *sodium chloride R* in *water R* and dilute to 100 mL with the same solvent.

Storage: at 2 °C to 8 °C; use within 3 days.

Tripotassium phosphate trihydrate. $K_3PO_4,3H_2O$. (M_r 266.3). *1155300.* [22763-03-7].

White or almost white crystalline powder, freely soluble in water.

Trisodium phosphate dodecahydrate. $Na_3PO_4,12H_2O$. (M_r 380.1). *1094300.* [10101-89-0].

Colourless or white or almost white crystals, freely soluble in water.

Tropic acid. $C_9H_{10}O_3$. (M_r 166.17). *1172000.* [529-64-6]. (2*RS*)-3-hydroxy-2-phenylpropanoic acid.

Troxerutin. $C_{33}H_{42}O_{19}$. (M_r 743). *1160300.* [7085-55-4]. Trihydroxyethylrutin. 3′,4′,7-Tris[*O*-(2-hydroxyethyl)]rutin. 2-[3,4-Bis(2-hydroxyethoxy)phenyl]-3-[[6-*O*-(6-deoxy-α-L-mannopyranosyl)-β-D-glucopyranosyl]oxy]-5-hydroxy-7-(2-hydroxyethoxy)-4*H*-1-benzopyran-4-one.

mp: 168 °C to 176 °C.

Trypsin. *1094500.* [9002-07-7].

A proteolytic enzyme obtained by activation of trypsinogen extracted from the pancreas of beef (*Bos taurus* L.).

White or almost white, crystalline or amorphous powder, sparingly soluble in water.

Trypsin for peptide mapping. *1094600.* [9002-07-7].

Trypsin of high purity treated to eliminate chymotryptic activity.

Tryptophan. $C_{11}H_{12}N_2O_2$. (M_r 204.2). *1094700.* [73-22-3].

White or yellowish-white, crystalline powder or colourless crystals, slightly soluble in water, very slightly soluble in ethanol (96 per cent).

$[\alpha]_D^{20}$: about −30, determined on a 10 g/L solution.

Tyramine. $C_8H_{11}NO$. (M_r 137.2). *1117600.* [51-67-2]. 4-(2-Aminoethyl)phenol.

Crystals, sparingly soluble in water, soluble in boiling anhydrous ethanol.

mp: 164 °C to 165 °C.

Tyrosine. $C_9H_{11}NO_3$. (M_r 181.2). *1094800.* [60-18-4]. 2-Amino-3-(4-hydroxyphenyl)propionic acid.

White or almost white, crystalline powder, or colourless or white or almost white crystals, slightly soluble in water, practically insoluble in acetone and in anhydrous ethanol, soluble in dilute hydrochloric acid and in solutions of alkali hydroxides.

Umbelliferone. $C_9H_6O_3$. (M_r 162.1). *1137500.* [93-35-6]. 7-Hydroxycoumarin. 7-Hydroxy-2*H*-1-benzopyran-2-one.

Needles from water.

mp: 225 °C to 228 °C.

Uracil. $C_4H_4N_2O_2$. (M_r 112.1). *1161800.* [66-22-8].

Content: minimum 95.0 per cent.

Urea. *1095000.* [57-13-6].

See *Urea (0743)*.

Uridine. $C_9H_{12}N_2O_6$. (M_r 244.2). *1095100.* [58-96-8]. 1-β-D-Ribofuranosyluracil.

White or almost white, crystalline powder, soluble in water.

mp: about 165 °C.

Ursolic acid. $C_{30}H_{48}O_3$. (M_r 456.7). *1141600.* [77-52-1]. (3β)-3-Hydroxyurs-12-en-28-oic acid.

White or almost white powder, practically insoluble in water, sparingly soluble in methanol, slightly soluble in ethanol (96 per cent).

$[\alpha]_D^{21}$: about 67.50, determined on a 10 g/L solution in a 56.1 g/L solution of *potassium hydroxide R* in *ethanol (96 per cent) R*.

mp: 285 °C to 288 °C.

Valencene. $C_{15}H_{24}$. (M_r 204.4). *1152100.* [4630-07-3]. 4β*H*,5α-Eremophila-1(10),11-diene. (1*R*,7*R*,8a*S*)-1,8a-Dimethyl-7-(1-methylethenyl)-1,2,3,5,6,7,8,8a-octahydronaphthalene.

Oily, colourless or pale yellow liquid, with a characteristic odour, practically insoluble in water, soluble in ethanol (96 per cent).

d_4^{20}: about 0.918.

n_D^{20}: about 1.508.

bp: about 123 °C.

Valencene used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Sweet orange oil (1811)*.

Content: minimum 80 per cent, calculated by the normalisation procedure.

Valerenic acid. $C_{15}H_{22}O_2$. (M_r 234.3). *1165700.* [3569-10-6]. (2*E*)-3-[(4*S*,7*R*,7a*R*)-3,7-Dimethyl-2,4,5,6,7,7a-hexahydro-1*H*-inden-4-yl]-2-methylprop-2-enoic acid.

mp: 134 °C to 138 °C.

Valeric acid. $C_5H_{10}O_2$. (M_r 102.1). *1095200.* [109-52-4]. Pentanoic acid.

Colourless liquid, soluble in water, freely soluble in ethanol (96 per cent).

d_{20}^{20}: about 0.94.

n_D^{20}: about 1.409.

bp: about 186 °C.

Vanillin. *1095300.* [121-33-5].

See *Vanillin (0747)*.

Vanillin reagent. *1095301.*

Carefully add, dropwise, 2 mL of *sulfuric acid R* to 100 mL of a 10 g/L solution of *vanillin R* in *ethanol (96 per cent) R*.

Storage: use within 48 h.

Vanillin solution, phosphoric. *1095302.*

Dissolve 1.0 g of *vanillin R* in 25 mL of *ethanol (96 per cent) R*. Add 25 mL of *water R* and 35 mL of *phosphoric acid R*.

Veratrole. $C_8H_{10}O_2$. (M_r 138.2). *1165400.* [91-16-7]. 1,2-Dimethoxybenzene.

d_4^{20}: 1.085.

n_D^{20}: 1.534.

bp: about 206 °C.

mp: about 22 °C.

Verbenone. $C_{10}H_{14}O$. (M_r 150.2). *1140500.* [1196-01-6]. (1*S*,5*S*)-4,6,6-Trimethylbicyclo[3.1.1]hept-3-en-2-one.

Oil with a characteristic odour, practically insoluble in water, miscible with organic solvents.

d_{20}^{20}: about 0.978.

n_D^{18}: about 1.49.

$[\alpha]_D^{18}$: about + 249.6.

bp: 227 °C to 228 °C.

mp: about 6.5 °C.

Verbenone used in gas chromatography complies with the following additional test.

Assay. Gas chromatography (*2.2.28*) as prescribed in the monograph *Rosemary oil (1846).*

Content: minimum 99 per cent, calculated by the normalisation procedure.

Vinyl acetate. $C_4H_6O_2$. (M_r 86,10). *1111800.* [108-05-4]. Ethenyl acetate.

d_{20}^{20}: about 0.930.

bp: about 72 °C.

Vinyl chloride. C_2H_3Cl. (M_r 62.5). *1095400.* [75-01-4].

Colourless gas, slightly soluble in organic solvents.

Vinyl polymer for chromatography, octadecyl. *1155400.*

Spherical particles (5 µm) of a vinyl alcohol copolymer chemically modified by bonding of octadecyl groups on the hydroxyl groups.

Vinyl polymer for chromatography, octadecylsilyl. *1121600.*

Spherical particles (5 µm) of a vinyl alcohol copolymer bonded to an octadecylsilane. Carbon content of 17 per cent.

2-Vinylpyridine. C_7H_7N. (M_r 105.1). *1102200.* [100-69-6].

Yellow liquid, miscible in water.

d_{20}^{20}: about 0.97.

n_D^{20}: about 1.549.

1-Vinylpyrrolidin-2-one. C_6H_9NO. (M_r 111.1). *1111900.* [88-12-0]. 1-Ethenylpyrrolidin-2-one.

Content: minimum 99.0 per cent.

Clear colourless liquid.

Water (*2.5.12*): maximum 0.1 per cent, determined on 2.5 g. Use as the solvent, a mixture of 50 mL of *anhydrous methanol R* and 10 mL of *butyrolactone R*.

Assay. Gas chromatography (*2.2.28*): use the normalisation procedure.

Column:

– *material*: fused-silica;
– *size*: *l* = 30 m, Ø = 0.5 mm;
– *stationary phase*: *macrogol 20 000 R.*

Carrier gas: *helium for chromatography R.*

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 1	80
	1 - 12	80 → 190
	12 - 27	190
Injection port		190

Detection: flame-ionisation.

Injection: 0.3 µL of the substance to be examined.

Adjust the flow rate of the carrier gas so that the retention time of the peak corresponding to 1-vinylpyrrolidin-2-one is about 17 min.

Vitexin. $C_{21}H_{20}O_{10}$. (M_r 448.4). *1133300.* [3681-93-4]. Apigenin 8-glucoside.

Yellow powder.

Storage: in an airtight container, protected from light.

Water. *1095500.* [7732-18-5].

See *Purified water (0008).*

Water R1. *1095509.*

Prepared from *distilled water R* by multiple distillation. Remove carbon dioxide by boiling for at least 15 min before use in a boiling flask of fused silica or borosilicate glass and cool. Any other suitable method may be used. The boiling flask has been already used for the test or has been filled with *water R* and kept in an autoclave at 121 °C for at least 1 h prior to first use. When tested immediately before use, *water R1* is neutral to *methyl red solution R*, i.e. it shall produce an orange-red (not a violet-red or yellow) colour corresponding to pH 5.5 ± 0.1 when 0.05 mL of *methyl red solution R* is added to 50 mL of the water to be examined.

Conductivity: maximum 1 µS·cm^{-1}, determined at 25 °C by an in-line conductivity meter (see *Purified water (0008)*).

Water, ammonium-free. *1095501.*

To 100 mL of *water R* add 0.1 mL of *sulfuric acid R*. Distil using the apparatus described for the determination of *Distillation range* (*2.2.11*). Reject the first 10 mL and collect the following 50 mL.

Water, carbon dioxide-free. *1095502.*

Water R which has been boiled for a few minutes and protected from the atmosphere during cooling and storage.

Water for chromatography. *1095503.*

Deionised *water R* with a resistivity of not less than 0.18 Mohm·m.

Water, distilled. *1095504.*

Water R prepared by distillation.

Water, distilled, deionised. *1095508.*

Deionised *water R* prepared by distillation with a resistivity of not less than 0.18 Mohm·m.

Water for injections. *1095505.*

See *Water for injections (0169).*

Water, nitrate-free. *1095506.*

To 100 mL of *water R* add a few milligrams of *potassium permanganate R* and of *barium hydroxide R*. Distil using the apparatus described for the determination of *Distillation range* (*2.2.11*). Reject the first 10 mL and collect the following 50 mL.

Water, particle-free. *1095507.*

Filter *water R* through a membrane with a pore size of 0.22 µm.

Weak cationic resin. *1096000.*

Polymethacrylic resin, slightly acid, with carboxyl groups present in a protonated form.

Particle size: 75 µm to 160 µm.

pH limits of use: 5 to 14.

Maximum temperature of use: 120 °C.

Xanthydrol. $C_{13}H_{10}O_2$. (M_r 198.2). *1096100.* [90-46-0]. 9-Xanthenol.

Content: minimum 90.0 per cent.

White or pale-yellow powder, very slightly soluble in water, soluble in ethanol (96 per cent) and in glacial acetic acid.

It is also available as a methanolic solution containing 90 g/L to 110 g/L of xanthydrol.

mp: about 123 °C.

Assay. In a 250 mL flask dissolve 0.300 g in 3 mL of *methanol R* or use 3.0 mL of solution. Add 50 mL of *glacial acetic acid R* and, dropwise with shaking, 25 mL of a 20 g/L solution of *urea R*. Allow to stand for 12 h, collect the precipitate on a sintered-glass filter (16) (*2.1.2*), wash with 20 mL of *ethanol (96 per cent) R*, dry in an oven at 100 °C to 105 °C and weigh.

1 g of precipitate is equivalent to 0.9429 g of xanthydrol.

Storage: protected from light. If a methanolic solution is used, store in small sealed ampoules and filter before use if necessary.

Xanthydrol R1. *1096101.*

Complies with the requirements prescribed for *xanthydrol R* with the following requirement.

Content: minimum 98.0 per cent of $C_{13}H_{10}O_2$.

Xanthydrol solution. *1096102.*

To 0.1 mL of a 100 g/L solution of *xanthydrol R* in *methanol R* add 100 mL of *anhydrous acetic acid R* and 1 mL of *hydrochloric acid R*. Allow to stand for 24 h before using.

Xylene. C_8H_{10}. (M_r 106.2). *1096200.* [1330-20-7].

Mixture of isomers. Clear, colourless, flammable liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.867.

n_D^{20}: about 1.497.

bp: about 138 °C.

***m*-Xylene.** C_8H_{10}. (M_r 106.2). *1117700.* [108-38-3].
1,3-Dimethylbenzene.

Clear, colourless, flammable liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.884.

n_D^{20}: about 1.497.

bp: about 139 °C.

mp: about – 47 °C.

***o*-Xylene.** C_8H_{10}. (M_r 106.2). *1100600.* [95-47-6].
1,2-Dimethylbenzene.

Clear, colourless, flammable liquid, practically insoluble in water, miscible with ethanol (96 per cent).

d_{20}^{20}: about 0.881.

n_D^{20}: about 1.505.

bp: about 144 °C.

mp: about – 25 °C.

Xylenol orange. $C_{31}H_{28}N_2Na_4O_{13}S$. ($M_r$ 761). *1096300.* [3618-43-7]. Tetrasodium 3,3′-(3*H*-2,1-benzoxathiol-3-ylidene)bis[(6-hydroxy-5-methyl-3,1-phenylene)methyleneiminobisacetate] *S,S*-dioxide.

Reddish-brown crystalline powder, soluble in water.

Xylenol orange triturate. *1096301.*

Triturate 1 part of *xylenol orange R* with 99 parts of *potassium nitrate R*.

Test for sensitivity. To 50 mL of *water R* add 1 mL of *dilute acetic acid R*, 50 mg of the xylenol orange triturate and 0.05 mL of *lead nitrate solution R*. Add *hexamethylenetetramine R* until the colour changes from yellow to violet-red. After addition of 0.1 mL of *0.1 M sodium edetate* the colour changes to yellow.

Xylose. *1096400.* [58-86-6].

See *Xylose (1278)*.

Zinc. Zn. (A_r 65.4). *1096500.* [7440-66-6].

Content: minimum 99.5 per cent.

Silver-white cylinders, granules, pellets or filings with a blue sheen.

Arsenic (*2.4.2, Method A*): maximum 0.2 ppm.

Dissolve 5.0 g in a mixture of the 15 mL of *hydrochloric acid R* and 25 mL of *water R* prescribed.

Zinc, activated. *1096501.*

Place the zinc cylinders or pellets to be activated in a conical flask and add a sufficient quantity of a 50 ppm solution of *chloroplatinic acid R* to cover the metal. Allow the metal to remain in contact with the solution for 10 min, wash, drain and dry immediately.

Arsenic (*2.4.2, Method A*). To 5 g of the activated zinc add 15 mL of *hydrochloric acid R*, 25 mL of *water R*, 0.1 mL of *stannous chloride solution R* and 5 mL of *potassium iodide solution R*. No stain is produced on the *mercuric bromide paper R*.

Activity. Repeat the test for arsenic using the same reagents and adding a solution containing 1 µg of arsenic. An appreciable stain appears on the *mercuric bromide paper R*.

Zinc acetate. $(C_2H_3O_2)_2Zn,2H_2O$. (M_r 219.5). *1102300.* [5970-45-6]. Zinc acetate dihydrate.

Bright white or almost white crystals, slightly efflorescent, freely soluble in water, soluble in ethanol (96 per cent). It loses its crystallisation water at 100 °C.

d_{20}^{20}: about 1.735.

mp: about 237 °C.

Zinc acetate solution. *1102301.*

Mix 600 mL of *water R* with 150 mL of *glacial acetic acid R*, 54.9 g of *zinc acetate R* and stir to dissolve. Continue stirring while adding 150 mL of *concentrated ammonia R*. Cool to room temperature and adjust with *ammonia R* to pH 6.4. Dilute the mixture to 1 L with *water R*.

Zinc chloride. *1096600.* [7646-85-7].

See *Zinc chloride (0110)*.

Zinc chloride-formic acid solution. *1096601.*

Dissolve 20 g of *zinc chloride R* in 80 g of an 850 g/L solution of *anhydrous formic acid R*.

Zinc chloride solution, iodinated. *1096602.*

Dissolve 20 g of *zinc chloride R* and 6.5 g of *potassium iodide R* in 10.5 mL of *water R*. Add 0.5 g of *iodine R* and shake for 15 min. Filter if necessary.

Storage: protected from light.

Zinc iodide and starch solution. *1096502.*

To a solution of 2 g of *zinc chloride R* in 10 mL of *water R* add 0.4 g of *soluble starch R* and heat until the starch has dissolved. After cooling to room temperature add 1.0 mL of a colourless solution containing 0.10 g *zinc R* as filings and 0.2 g of *iodine R* in *water R*. Dilute the solution to 100 mL with *water R* and filter.

Storage: protected from light.

Test for sensitivity. Dilute 0.05 mL of *sodium nitrite solution R* to 50 mL with *water R*. To 5 mL of this solution add 0.1 mL of *dilute sulfuric acid R* and 0.05 mL of the zinc iodide and starch solution and mix. The solution becomes blue.

Zinc oxide. *1096700.* [1314-13-2].

See *Zinc oxide (0252)*.

Zinc powder. Zn. (A_r 65.4). *1096800.* [7440-66-6].

Content: minimum 90.0 per cent.

Very fine, grey powder, soluble in *dilute hydrochloric acid R*.

Zinc sulfate. *1097000.* [7446-20-0].

See *Zinc sulfate (0111)*.

Zirconyl chloride. A basic salt corresponding approximately to the formula $ZrCl_2O,8H_2O$. *1097100.* [15461-27-5].

Content: minimum 96.0 per cent of $ZrCl_2O,8H_2O$.

White or almost white, crystalline powder or crystals, freely soluble in water and in ethanol (96 per cent).

Assay. Dissolve 0.600 g in a mixture of 5 mL of *nitric acid R* and 50 mL of *water R*. Add 50.0 mL of *0.1 M silver nitrate* and 3 mL of *dibutyl phthalate R* and shake. Using 2 mL of *ferric ammonium sulfate solution R2* as indicator, titrate with *0.1 M ammonium thiocyanate* until a reddish-yellow colour is obtained.

1 mL of *0.1 M silver nitrate* is equivalent to 16.11 mg of $ZrCl_2O,8H_2O$.

Zirconyl nitrate. A basic salt corresponding approximately to the formula $ZrO(NO_3)_2,2H_2O$. *1097200.* [14985-18-3].

A white or almost white powder or crystals, hygroscopic, soluble in water. The aqueous solution is a clear or at most slightly opalescent liquid.

Storage: in an airtight container.

Zirconyl nitrate solution. *1097201.*

A 1 g/L solution in a mixture of 40 mL of *water R* and 60 mL of *hydrochloric acid R*.

04/2010:40102

4.1.2. STANDARD SOLUTIONS FOR LIMIT TESTS

Acetaldehyde standard solution (100 ppm C_2H_4O). *5000100.*

Dissolve 1.0 g of *acetaldehyde R* in *2-propanol R* and dilute to 100.0 mL with the same solvent. Dilute 5.0 mL of the solution to 500.0 mL with *2-propanol R*. Prepare immediately before use.

Acetaldehyde standard solution (100 ppm C_2H_4O) R1. *5000101.*

Dissolve 1.0 g of *acetaldehyde R* in *water R* and dilute to 100.0 mL with the same solvent. Dilute 5.0 mL of the solution to 500.0 mL with *water R*. Prepare immediately before use.

Aluminium standard solution (200 ppm Al). *5000200.*

Dissolve in *water R* a quantity of *aluminium potassium sulfate R* equivalent to 0.352 g of $AlK(SO_4)_2,12H_2O$. Add 10 mL of *dilute sulfuric acid R* and dilute to 100.0 mL with *water R*.

Aluminium standard solution (100 ppm Al). *5000203.*

Immediately before use, dilute with *water R* to 10 times its volume a solution containing 8.947 g of *aluminium chloride R* in 1000.0 mL of *water R*.

Aluminium standard solution (10 ppm Al). *5000201.*

Immediately before use, dilute with *water R* to 100 times its volume in a solution containing *aluminium nitrate R* equivalent to 1.39 g of $Al(NO_3)_3,9H_2O$ in 100.0 mL.

Aluminium standard solution (2 ppm Al). *5000202.*

Immediately before use, dilute with *water R* to 100 times its volume a solution containing *aluminium potassium sulfate R* equivalent to 0.352 g of $AlK(SO_4)_2,12H_2O$ and 10 mL of *dilute sulfuric acid R* in 100.0 mL.

Ammonium standard solution (100 ppm NH_4). *5000300.*

Immediately before use, dilute to 25 mL with *water R* 10 mL of a solution containing *ammonium chloride R* equivalent to 0.741 g of NH_4Cl in 1000 mL.

Ammonium standard solution (3 ppm NH_4). *5006100.*

Immediately before use, dilute with *water R* to 100 times its volume a solution containing *ammonium chloride R* equivalent to 0.889 g of NH_4Cl in 1000.0 mL.

Ammonium standard solution (2.5 ppm NH_4). *5000301.*

Immediately before use, dilute with *water R* to 100 times its volume a solution containing *ammonium chloride R* equivalent to 0.741 g of NH_4Cl in 1000.0 mL.

Ammonium standard solution (1 ppm NH_4). *5000302.*

Immediately before use, dilute *ammonium standard solution (2.5 ppm NH_4) R* to 2.5 times its volume with *water R*.

Antimony standard solution (100 ppm Sb). *5000401.*

Dissolve *antimony potassium tartrate R* equivalent to 0.274 g of $C_4H_4KO_7\,Sb,{}^1/_2H_2O$ in 500 mL of *1M hydrochloric acid* and dilute the clear solution to 1000 mL with *water R*.

Antimony standard solution (1 ppm Sb). *5000400.*

Dissolve *antimony potassium tartrate R* equivalent to 0.274 g of $C_4H_4KO_7Sb,{}^1/_2H_2O$ in 20 mL of *hydrochloric acid R1* and dilute the clear solution to 100.0 mL with *water R*. To 10.0 mL of this solution add 200 mL of *hydrochloric acid R1* and dilute to 1000.0 mL with *water R*. To 100.0 mL of this solution add 300 mL of *hydrochloric acid R1* and dilute to 1000.0 mL with *water R*. Prepare the dilute solutions immediately before use.

Arsenic standard solution (10 ppm As). *5000500.*

Immediately before use, dilute with *water R* to 100 times its volume a solution prepared by dissolving *arsenious trioxide R* equivalent to 0.330 g of As_2O_3 in 5 mL of *dilute sodium hydroxide solution R* and diluting to 250.0 mL with *water R*.

Arsenic standard solution (1 ppm As). *5000501.*

Immediately before use, dilute *arsenic standard solution (10 ppm As) R* to 10 times its volume with *water R*.

Arsenic standard solution (0.1 ppm As). *5000502.*

Immediately before use, dilute *arsenic standard solution (1 ppm As) R* to 10 times its volume with *water R*.

Barium standard solution (0.1 per cent Ba). *5000601.*

Dissolve *barium chloride R* equivalent to 0.178 g of $BaCl_2,2H_2O$ in *distilled water R* and dilute to 100.0 mL with the same solvent.

Barium standard solution (50 ppm Ba). *5000600.*

Immediately before use, dilute with *distilled water R* to 20 times its volume a solution in *distilled water R* containing *barium chloride R* equivalent to 0.178 g of $BaCl_2,2H_2O$ in 100.0 mL.

Barium standard solution (2 ppm Ba). *5005600.*

Immediately before use, dilute *barium standard solution (50 ppm Ba) R* to 25 times its volume with *distilled water R*.

Bismuth standard solution (100 ppm Bi). *5005300.*

Dissolve *bismuth R* equivalent to 0.500 g of Bi in 50 mL of *nitric acid R* and dilute to 500.0 mL with *water R*. Dilute the solution to 10 times its volume with *dilute nitric acid R* immediately before use.

Cadmium standard solution (0.1 per cent Cd). *5000700.*

Dissolve *cadmium R* equivalent to 0.100 g of Cd in the smallest necessary amount of a mixture of equal volumes of *hydrochloric acid R* and *water R* and dilute to 100.0 mL with a 1 per cent *V/V* solution of *hydrochloric acid R*.

Cadmium standard solution (10 ppm Cd) . *5000701.*

Immediately before use, dilute *cadmium standard solution (0.1 per cent Cd) R* to 100 times its volume with a 1 per cent *V/V* solution of *hydrochloric acid R*.

Calcium standard solution (400 ppm Ca). *5000800.*

Immediately before use, dilute with *distilled water R* to 10 times its volume a solution in *distilled water R* containing *calcium carbonate R* equivalent to 1.000 g of $CaCO_3$ and 23 mL of *1 M hydrochloric acid* in 100.0 mL.

Calcium standard solution (100 ppm Ca). *5000801.*

Immediately before use, dilute with *distilled water R* to 10 times its volume a solution in *distilled water R* containing *calcium carbonate R* equivalent to 0.624 g of $CaCO_3$ and 3 mL of *acetic acid R* in 250.0 mL.